SECTION L - INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS

Updated through FAC 2001-24
Last updated: 7/19/2004

***Note to Offerors*: General guidance regarding the applicability of the following information is provided below. Specific information required to be complete or supplement any of the applicable items will be included in the specific RFP.**

This SECTION is made up of four parts as follows:

I. General Information
II. General Instructions
III. Technical Proposal Instructions
IV. Business Proposal Instructions

I. General Information

Item 1:	*The following provision is applicable to all competitive solicitations that will result in a contract over $100,000.* **INSTRUCTIONS TO OFFERORS–COMPETITIVE ACQUISITION** [FAR Clause 52.215-1 (January 2004)] (a) *Definitions*. As used in this provision-- *"Discussions"* are negotiations that occur after establishment of the competitive range that may, at the Contracting Officer's discretion, result in the offeror being allowed to revise its proposal. *"In writing"*, *"writing"*, or *"written"* means any worded or numbered expression that can be read, reproduced, and later communicated, and includes electronically transmitted and stored information. "*Proposal modification*" is a change made to a proposal before the solicitation's closing date and time, or made in response to an amendment, or made to correct a mistake at any time before award. "*Proposal revision*" is a change to a proposal made after the solicitation closing date, at the request of or as allowed by a Contracting Officer as the result of negotiations. "*Time,*" if stated as a number of days, is calculated using calendar days, unless otherwise specified, and will include Saturdays, Sundays, and legal holidays. However, if the last day falls on a Saturday, Sunday, or legal holiday, then the period shall include the next working day. (b) *Amendments to solicitations*. If this solicitation is amended, all terms and conditions that are not amended remain unchanged. Offerors shall acknowledge receipt of any amendment to this solicitation by the date and time specified in the amendment(s). (c) *Submission, modification, revision, and withdrawal of proposals*. (1) Unless other methods (*e.g.*, electronic commerce or facsimile) are permitted in the solicitation, proposals and modifications to proposals shall be submitted in paper media in sealed envelopes or packages (i) addressed to the office specified in the solicitation, and (ii) showing the time and date specified for receipt, the solicitation number, and the name and address of the offeror. Offerors using commercial carriers should ensure that the proposal is marked on the outermost wrapper with the information in paragraphs (c)(1)(i) and (c)(1)(ii) of this provision. (2) The first page of the proposal must show-- (i) The solicitation number; (ii) The name, address, and telephone and facsimile numbers of the offeror (and electronic address if available); (iii) A statement specifying the extent of agreement with all terms, conditions, and provisions included in the solicitation and agreement to furnish any or all items upon which prices are offered at the price set opposite each item;

(iv) Names, titles, and telephone and facsimile numbers (and electronic addresses if available) of persons authorized to negotiate on the offeror's behalf with the Government in connection with this solicitation; and

(v) Name, title, and signature of person authorized to sign the proposal. Proposals signed by an agent shall be accompanied by evidence of that agent's authority, unless that evidence has been previously furnished to the issuing office.

(3) *Submission, modification, revision, and withdrawal of proposals*. (i) Offerors are responsible for submitting proposals, and any modifications or revisions, so as to reach the Government office designated in the solicitation by the time specified in the solicitation. If no time is specified in the solicitation, the time for receipt is 4:30 p.m., local time, for the designated Government office on the date that proposal or revision is due.

(ii) (A) Any proposal, modification, or revision received at the Government office designated in the solicitation after the exact time specified for receipt of offers is "late" and will not be considered unless it is received before award is made, the Contracting Officer determines that accepting the late offer would not unduly delay the acquisition; and--

(*1*) If it was transmitted through an electronic commerce method authorized by the solicitation, it was received at the initial point of entry to the Government infrastructure not later than 5:00 p.m. one working day prior to the date specified for receipt of proposals; or

(*2*) There is acceptable evidence to establish that it was received at the Government installation designated for receipt of offers and was under the Government's control prior to the time set for receipt of offers; or

(*3*) It is the only proposal received.

(B) However, a late modification of an otherwise successful proposal that makes its terms more favorable to the Government, will be considered at any time it is received and may be accepted.

(iii) Acceptable evidence to establish the time of receipt at the Government installation includes the time/date stamp of that installation on the proposal wrapper, other documentary evidence of receipt maintained by the installation, or oral testimony or statements of Government personnel.

(iv) If an emergency or unanticipated event interrupts normal Government processes so that proposals cannot be received at the office designated for receipt of proposals by the exact time specified in the solicitation, and urgent Government requirements preclude amendment of the solicitation, the time specified for receipt of proposals will be deemed to be extended to the same time of day specified in the solicitation on the first work day on which normal Government processes resume.

(v) Proposals may be withdrawn by written notice received at any time before award. Oral proposals in response to oral solicitations may be withdrawn orally. If the solicitation authorizes facsimile proposals, proposals may be withdrawn via facsimile received at any time before award, subject to the conditions specified in the provision at 52.215-5, Facsimile Proposals. Proposals may be withdrawn in person by an offeror or an authorized representative, if the identity of the person requesting withdrawal is established and the person signs a receipt for the proposal before award.

(4) Unless otherwise specified in the solicitation, the offeror may propose to provide any item or combination of items.

(5) Offerors shall submit proposals in response to this solicitation in English, unless otherwise permitted by the solicitation, and in U.S. dollars, unless the provision at FAR 52.225-17, Evaluation of Foreign Currency Offers, is included in the solicitation.

(6) Offerors may submit modifications to their proposals at any time before the solicitation closing date and time, and may submit modifications in response to an amendment, or to correct a mistake at any time before award.

(7) Offerors may submit revised proposals only if requested or allowed by the Contracting Officer.

(8) Proposals may be withdrawn at any time before award. Withdrawals are effective upon receipt of notice by the Contracting Officer.

(d) *Offer expiration date*. Proposals in response to this solicitation will be valid for the number of days specified on the solicitation cover sheet (unless a different period is proposed by the offeror).

[Note: In accordance with HHSAR 352.215-1, the following paragraph (e) is substituted for the subparagraph (e) of the provision at FAR 52.215-1.]

(e) *Restriction on disclosure and use of data*. (1) The proposal submitted in response to this request may contain data (trade secrets; business data, e.g., commercial information, financial information, and cost and pricing data; and technical data) which the offeror, including its prospective subcontractor(s), does not want used or disclosed for any purpose other than for evaluation of the proposal. The use and disclosure of any data may be so restricted; provided, that the Government determines that the data is not required to be disclosed under the Freedom of Information Act, 5 U.S.C. 552, as amended, and the offeror marks the cover sheet of the proposal with the following legend, specifying the particular portions of the proposal which are to be restricted in accordance with the conditions of the legend. The Government's determination to withhold or disclose a record will be based upon the particular circumstances involving the record in question and whether the record may be exempted from disclosure under the Freedom of Information Act. The legend reads:

> Unless disclosure is required by the Freedom of Information Act, 5 U.S.C. 552, as amended, (the Act) as determined by Freedom of Information (FOI) officials of the Department of Health and Human Services, data contained in the portions of this proposal which have been specifically identified by page number, paragraph, etc. by the offeror as containing restricted information shall not be used or disclosed except for evaluation purposes.
>
> The offeror acknowledges that the Department may not be able to withhold a record (data, document, etc.) nor deny access to a record requested pursuant to the Act and that the Department's FOI officials must make that determination. The offeror hereby agrees that the Government is not liable for disclosure if the Department has determined that disclosure is required by the Act.
>
> If a contract is awarded to the offeror as a result of, or in connection with, the submission of this proposal, the Government shall have right to use or disclose the data to the extent provided in the contract. Proposals not resulting in a contract remain subject to the Act.
>
> The offeror also agrees that the Government is not liable for disclosure or use of unmarked data and may use or disclose the data for any purpose, including the release of the information pursuant to requests under the Act. The data subject to this restriction are contained in pages (insert page numbers, paragraph designations, etc. or other identification).

(2) In addition, the offeror should mark each page of data it wishes to restrict with the following statement:

> "Use or disclosure of data contained on this page is subject to the restriction on the cover sheet of this proposal or quotation."

(3) Offerors are cautioned that proposals submitted with restrictive legends or statements differing in substance from the above legend may not be considered for award. The Government reserves the right to reject any proposal submitted with a nonconforming legend.

(f) *Contract award*. (1) The Government intends to award a contract or contracts resulting from this solicitation to the responsible offeror(s) whose proposal(s) represents the best value after

	evaluation in accordance with the factors and subfactors in the solicitation. (2) The Government may reject any or all proposals if such action is in the Government's interest. (3) The Government may waive informalities and minor irregularities in proposals received. (4) The Government intends to evaluate proposals and award a contract without discussions with offerors (except clarifications as described in FAR 15.306(a)). Therefore, the offeror's initial proposal should contain the offeror's best terms from a cost or price and technical standpoint. The Government reserves the right to conduct discussions if the Contracting Officer later determines them to be necessary. If the Contracting Officer determines that the number of proposals that would otherwise be in the competitive range exceeds the number at which an efficient competition can be conducted, the Contracting Officer may limit the number of proposals in the competitive range to the greatest number that will permit an efficient competition among the most highly rated proposals. (5) The Government reserves the right to make an award on any item for a quantity less than the quantity offered, at the unit cost or prices offered, unless the offeror specifies otherwise in the proposal. (6) The Government reserves the right to make multiple awards if, after considering the additional administrative costs, it is in the Government's best interest to do so. (7) Exchanges with offerors after receipt of a proposal do not constitute a rejection or counteroffer by the Government. (8) The Government may determine that a proposal is unacceptable if the prices proposed are materially unbalanced between line items or subline items. Unbalanced pricing exists when, despite an acceptable total evaluated price, the price of one or more contract line items is significantly overstated or understated as indicated by the application of cost or price analysis techniques. A proposal may be rejected if the Contracting Officer determines that the lack of balance poses an unacceptable risk to the Government. (9) If a cost realism analysis is performed, cost realism may be considered by the source selection authority in evaluating performance or schedule risk. (10) A written award or acceptance of proposal mailed or otherwise furnished to the successful offeror within the time specified in the proposal shall result in a binding contract without further action by either party. (11) If a post-award debriefing is given to requesting offerors, the Government shall disclose the following information, if applicable: (i) The agency's evaluation of the significant weak or deficient factors in the debriefed offeror's offer. (ii) The overall evaluated cost or price and technical rating of the successful and debriefed offeror and past performance information on the debriefed offeror. (iii) The overall ranking of all offerors, when any ranking was developed by the agency during source selection; (iv) A summary of the rationale for award. (v) For acquisitions of commercial items, the make and model of the item to be delivered by the successful offeror. (vi) Reasonable responses to relevant questions posed by the debriefed offeror as to whether source-selection procedures set forth in the solicitation, applicable regulations, and other applicable authorities were followed by the agency. (End of Provision)
Item 2:	*If this item is applicable, SECTION L.1. of the specific RFP shall so state.* **Alternate I** (October 1997). As prescribed in 15.209(a)(1), substitute the following paragraph (f)(4) for paragraph (f)(4) of the basic provision:

	(f) (4) The Government intends to evaluate proposals and award a contract after conducting discussions with offerors whose proposals have been determined to be within the competitive range. If the Contracting Officer determines that the number of proposals that would otherwise be in the competitive range exceeds the number at which an efficient competition can be conducted, the Contracting Officer may limit the number of proposals in the competitive range to the greatest number that will permit an efficient competition among the most highly rated proposals. Therefore, the offeror's initial proposal should contain the offeror's best terms from a price and technical standpoint.
Item 3:	*If this item is applicable, SECTION L.I. of the specific RFP shall so state.* **Alternate II** (October 1997). As prescribed in 15.209(a)(2), add a paragraph (c)(9) substantially the same as the following to the basic clause: (9) Offerors may submit proposals that depart from stated requirements. Such proposals shall clearly identify why the acceptance of the proposal would be advantageous to the Government. Any deviations from the terms and conditions of the solicitation, as well as the comparative advantage to the Government, shall be clearly identified and explicitly defined. The Government reserves the right to amend the solicitation to allow all offerors an opportunity to submit revised proposals based on the revised requirements.
Item 4:	*If this item is applicable, SECTION L.I. of the specific RFP shall so state.* **REQUEST FOR INFORMATION OR SOLICITATION FOR PLANNING PURPOSES** [FAR 52.215-3 (October 1997)] (a) The Government does not intend to award a contract on the basis of this solicitation or to otherwise pay for the information solicited except as an allowable cost under other contracts as provided in subsection 31.205-18, Bid and proposal costs, of the Federal Acquisition Regulation. (b) Although "proposal" and "offeror" are used in this Request for Information, your response will be treated as information only. It shall not be used as a proposal. (c) This solicitation is issued for the purpose of: *[the purpose will be stated in the specific RFP]* . (End of provision)
Item 5:	*If this item is applicable, SECTION L.I. of the specific RFP will identify pertinent information.* "**JUST IN TIME**" This RFP contains special procedures for the submission of business management proposals. These special procedures are designed to reduce the administrative burden on offerors without compromising the information needed during the initial evaluation of proposals. Certain documents will no longer be required to be submitted with initial proposals, but will be requested at a later stage in the competitive process. Specifically, the travel policy, the annual financial statement, the total compensation plan, the subcontracting plan, and certain types of cost/pricing information will only be required to be submitted from those offerors included in the competitive range, or the apparent successful offeror. The special procedures for submission of this documentation are set forth in detail below: **Travel Policy**. The offeror's (and any proposed subcontractor's) written travel policy shall **not** be submitted with the initial business proposal. All offerors included in the competitive range will be required to submit a travel policy as a part of their final proposal revision. **Annual Report**. The offeror's most recent annual report shall **not** be submitted with the initial business proposal. All offerors included in the competitive range will be required submit a copy of their most recent annual report as a part of their final proposal revision. **Total Compensation Plan**. The offeror's total compensation plan shall **not** be submitted with the initial business proposal. All offerors included in the competitive range will be required submit a total compensation plan as a part of their final proposal revision.

	Subcontracting Plan. The offeror's Small Business Subcontracting Plan shall **not** be submitted with the initial business proposal. Only those offerors included in the competitive range will be required to submit **an acceptable** subcontracting plan. **OR** **Subcontracting Plan**. The offeror's Small Business Subcontracting Plan shall **not** be submitted with the initial business proposal. Only the apparent successful offeror will be required to submit **an acceptable** subcontracting plan. **Cost/Pricing Information**. The offeror's business proposal shall include the basic cost/pricing information specified in Section L.2.c.(1) of this RFP. In addition, the Government may require offerors included in the competitive range to submit additional information substantiating their proposed costs or prices. This additional cost/pricing information will be requested after establishment of the competitive range, and potentially includes payroll documentation, vendor quotes, invoice prices, and/or any other information deemed necessary by the contracting officer to evaluate the reasonableness of the price or to determine cost realism. [The information may also include submission and certification of cost or pricing data.]
Item 6:	*If this item is applicable, SECTION L.1. of the specific RFP shall so state.* **NOTICE OF SMALL BUSINESS SET-ASIDE** (1) **General**. Bids or proposals under this procurement are solicited only from small business concerns. The procurement is to be awarded only to one or more such concerns, organizations, or individuals. This action is based on a determination by the Contracting Officer, alone or in conjunction with a representative of the Small Business Administration, that it is in the interest of maintaining or mobilizing the Nation's full productive capacity, or in the interest of war or national defense programs, or in the interest of assuring that a fair proportion of Government procurement is placed with small business concerns. Bids or proposals received from others will be considered non-responsive. (2) **Definitions**. The term "small business concern" means a concern, including its affiliates, which is independently owned and operated, is not dominant in the field of operation in which it is bidding on Government contracts, and can further qualify under the criteria set forth in the regulations of the Small Business Administration (13 CFR 121.3-8). In addition to meeting these criteria, a manufacturer or a regular dealer submitting bids or proposals in his own name must agree to furnish in the performance of the contract end items manufactured or produced in the United States, its territories and possessions, Commonwealth of Puerto Rico, the Trust Territory of the Pacific Islands, and the District of Columbia, by small business concerns. Provided, that this additional requirement does not apply in connection with construction or service contracts.
Item 7:	*If this item is applicable, SECTION L.1. of the specific RFP shall so state.* **NOTICE OF 8(a) COMPETITIVE SET-ASIDE** Offers are solicited only from small business concerns expressly certified by the Small Business Administration (SBA) for participation in the SBA's 8(a) Program. Bids or proposals received from others will be considered non-responsive.
Item 8:	*If this item is applicable, SECTION L.1. of the specific RFP shall so state.* **NOTICE OF SERVICE-DISABLED VETERAN-OWNED SMALL BUSINESS SET-ASIDE** In accordance with the "Service-Disabled Veteran-owned Small Business (SDVOSB) Procurement Program" authorized by the Veterans Benefit Act of 2003 (15 U.S.C. 657f), offers are solicited only from Service-Disabled Veteran-owned Small Business concerns. At the time of proposal submission, a service-disabled veteran-owned small business (SDVOSB) concern must represent to the Contracting Officer that it is a SDVOSB concern and is considered small under the North American Industry Classification System (NAICS) code assigned to the solicitation. Offers received from other than SDVOSB concerns shall not be considered.

Item 9:	*This item is applicable to all RFPs. SECTION L.I. of the specific RFP will identify applicable information required for this item.* **NAICS CODE AND SIZE STANDARD**
Item 10:	*This statement applies to all RFPs which are NOT Small Business or 8(a) set-asides.* **THIS REQUIREMENT IS NOT SET-ASIDE FOR SMALL BUSINESS.** However, the Federal Acquisition Regulation (FAR) requires in every solicitation, (except for foreign acquisitions) the inclusion of the North American Industry Classification System (NAICS) Code and corresponding size standard which best describes the nature of the requirement in the solicitation.
Item 11:	*This item applies to all competitive solicitations which are not Competitive 8(a) or Small Business set-asides. SECTION L.I. of the specific RFP will identify pertinent information required for this item.* In accordance with FAR Clause 52.219-23, Notice of Price Evaluation Adjustment for Small Disadvantaged Business Concerns, incorporated in Section I.3., offerors will be evaluated by adding a factor of *[percentage to be identified in the specific RFP]* percent to the price of all offers, except offers from small disadvantaged business concerns that have not waived the adjustment. (Note: A listing of other offerors who are excepted and will not have this evaluation factor added to their offer may be found in subparagraph (b) of FAR Clause 52.219-23. A small disadvantaged business concern may elect to waive the adjustment, in which case the factor will be added to its offer for evaluation purposes. The agreements in paragraph (d) of FAR Clause 52.219-23 do not apply to offerors that waive the adjustment. **AN OFFEROR WHO ELECTS TO WAIVE THIS EVALUATION ADJUSTMENT MUST SPECIFICALLY INDICATE WITH A STATEMENT TO THIS EFFECT ON THE COVER PAGE OF ITS BUSINESS PROPOSAL.**
Item 12:	*This item is applicable to all RFPs. SECTION L.I. of the specific RFP will identify applicable information required for this item.* **TYPE OF CONTRACT AND NUMBER OF AWARD(S)**
Item 13:	*If this item is applicable, SECTION L.I. of the specific RFP will identify pertinent information.* **PRE-PROPOSAL CONFERENCE** A pre-proposal conference will be held with prospective offerors at *[will be identified in the specific RFP]* on *[will be identified in the specific RFP]* . The pre-proposal conference will be held for the purpose of providing information concerning the Government's requirements which may be helpful in the preparation of proposals and for answering any questions which you have regarding this solicitation. The success of this type of conference depends largely on the lead-time available to the Government for research in connection with questions submitted by offerors. Therefore, you are requested to mail written questions concerning any areas of uncertainty which, in your opinion, require clarification or correction, in sufficient time to be received on or before *[will be identified in the specific RFP]* at the address cited in Attachment *[will be identified in the specific RFP]* . Your questions should be submitted to the contract specialist, *[will be identified in the specific RFP]* and the envelope should be marked, "Pre-proposal conference, RFP No. NCI-___." A set of all questions and answers will be furnished simultaneously to all prospective offerors whether or not they are in attendance. Because of space limitations, each prospective offeror shall be limited to a total of *[will be identified in the specific RFP]* representatives. Attendance at the pre-proposal conference is recommended; however, attendance is not a prerequisite for proposal submission and will not be considered a factor in proposal evaluation.

Item 14:	*If this item is applicable, SECTION L.I. of the specific RFP will identify pertinent information.* **ESTIMATE OF EFFORT**
Item 15:	*If this item is applicable, SECTION L.I. of the specific RFP will identify pertinent information.* **LEVEL OF EFFORT**
Item 16:	*This item is applicable to all RFPs.* **COMMITMENT OF PUBLIC FUNDS** The Contracting Officer is the only individual who can legally commit the Government to the expenditure of public funds in connection with the proposed procurement. Any other commitment, either explicit or implied, is invalid. **COMMUNICATIONS PRIOR TO CONTRACT AWARD** Offerors shall direct all communications to the attention of the Contract Specialist or Contracting Officer cited on the face page of this RFP. Communications with other officials may compromise the competitiveness of this acquisition and result in cancellation of the requirement. **RELEASE OF INFORMATION** Contract selection and award information will be disclosed to offerors in accordance with regulations applicable to negotiated acquisition. Prompt written notice will be given to unsuccessful offerors as they are eliminated from the competition, and to all offerors following award.
Item 17:	*This item is applicable to all RFPs. SECTION L.I. of the specific RFP will identify pertinent information required for this item.* **COMPARATIVE IMPORTANCE OF PROPOSALS**
Item 18:	*If this item is applicable, SECTION L.I. of the specific RFP will identify pertinent information.* **REFERENCE MATERIALS** A "reading room" containing reference materials pertinent to this acquisition is available in Room *[will be identified in the specific RFP]*, Executive Plaza South, 6120 Executive Boulevard, Rockville, Maryland, from *[will be identified in the specific RFP]* Monday through Friday (except Government holidays) through the closing date of the RFP. Use of the reading room is by appointment only; contact *[will be identified in the specific RFP]*, (301) 496-*[will be identified in the specific RFP]* for arrangements. Failure of offerors to examine the reference materials prior to proposal preparation and submission will be at the offeror's risk.
Item 19:	*If this item is applicable, SECTION L.I. of the specific RFP shall so state.* **CONCEPT REVIEW** This project has not been reviewed by the Board of Scientific Counselors as required. Such review will occur prior to technical evaluation. Thus potential offerors are cautioned that cancellation of this RFP due to disapproval by the Board of Scientific Counselors is a possibility.
Item 20:	*This item is applicable to all RFPs.* **PREPARATION COSTS** This RFP does not commit the Government to pay for the preparation and submission of a proposal. **SERVICE OF PROTEST** (AUGUST 1996) - FAR 52.233-2 (a) Protests, as defined in section 33.101 of the Federal Acquisition Regulation, that are filed directly

	with an agency, and copies of any protests that are filed with the General Accounting Office (GAO), shall be served on the Contracting Officer (addressed as follows) by obtaining written and dated acknowledgment of receipt from: Contracting Officer* Research Contracts Branch National Cancer Institute EPS, Room 6120 EXECUTIVE BLVD MSC BETHESDA MD 20892- (b) The copy of any protest shall be received in the office designated above within one day of filing a protest with the GAO. (End of Provision) **Complete address and contact information can be found on the SECTION A SOLICITATION/CONTRACT FORM page of the specific RFP.*
Item 21:	*If this item is applicable, SECTION L.I. of the specific RFP shall so state.* **LATE PROPOSALS AND REVISIONS**, HHSAR 352.215-70 Notwithstanding the procedures contained in FAR 52.215-1(c)(3) of the provision of this solicitation entitled Instructions to Offerors-Competitive Acquisition, a proposal received after the date specified for receipt may be considered if it offers significant cost or technical advantages to the Government; and it was received before proposals were distributed for evaluation, or within five calendar days after the exact time specified for receipt, whichever is earlier. (End of provision)
Item 22:	*If this item is applicable, SECTION L.I. of the specific RFP shall so state.* **AVAILABILITY OF THE "FEDERAL ADP AND TELECOMMUNICATIONS STANDARDS INDEX."** Copies of the "Federal ADP and Telecommunications Standards Index" can be purchased from the U.S. Government Printing Office, Superintendent of Documents, Washington, DC 20402.

II. General Instructions

Item 23: *This item is applicable to all RFPs.*

INTRODUCTION

The following instructions will establish the acceptable minimum requirements for the format and contents of proposals. Special attention is directed to the requirements for technical and business proposals to be submitted in accordance with these instructions.

(1) **Contract Type and General Clauses**

It is contemplated that a [cost-reimbursement (completion/level of effort)/fixed price] type contract will be awarded. (See General Information) Any resultant contract shall include the clauses applicable to the selected offeror's organization and type of contract awarded as required by Public Law, Executive Order, or acquisition regulations in effect at the time of execution of the proposed contract.

(2) **Authorized Official and Submission of Proposal**

The proposal must be signed by an official authorized to bind your organization and must stipulate that it is predicated upon all the terms and conditions of this RFP. Your proposal shall be submitted in the number of copies, to the addressees, and marked as indicated in the Attachment entitled, PACKAGING AND DELIVERY OF PROPOSAL, Part III, Section J hereof. Proposals will be typewritten, paginated, reproduced on letter size paper and will be legible in all required copies. To expedite the proposal evaluation, all documents required for responding to the RFP should be placed in the following order:

I. COVER PAGE

Include RFP title, number, name of organization, DUNS No., identification of the proposal part, and indicate whether the proposal is an original or a copy.

II. TECHNICAL PROPOSAL

It is recommended that the technical proposal consist of a cover page, a table of contents, and the information requested in the Technical Proposal Instructions and as specified in SECTION J, List of Attachments.

III. BUSINESS PROPOSAL

It is recommended that the business proposal consist of a cover page, a table of contents, and the information requested in the Business Proposal Instructions and as specified in SECTION J, List of Attachments.

(3) **Proposal Summary and Data Record (NIH-2043)**

The Offeror must complete the Form NIH-2043, attached, with particular attention to the length of time the proposal is firm and the designation of those personnel authorized to conduct negotiations. (See Section J, Attachment entitled, PROPOSAL SUMMARY AND DATA RECORD).

(4) **Separation of Technical and Business Proposals**

The proposal must be prepared in two parts: a "Technical Proposal" and a "Business Proposal." Each of the parts shall be separate and complete in itself so that evaluation of one may be accomplished independently of, and concurrently with, evaluation of the other. The technical proposal must include direct cost and resources information, such as labor-hours and categories and applicable rates, materials, subcontracts, travel, etc., and associated costs so that the offeror's understanding of the project may be evaluated (See Attachment entitled, TECHNICAL PROPOSAL COST INFORMATION/SUMMARY OF LABOR AND DIRECT COSTS).) However, the technical proposal should **not** include pricing data relating to individual salary information, indirect cost rates or amounts, fee amounts (if any)., and total costs. The technical proposal should disclose your technical approach in as much detail as possible, including, but not limited to, the requirements of the technical proposal instructions.

	(5) **Alternate Proposals** You may, at your discretion, submit alternate proposals, or proposals which deviate from the requirements; provided, that you also submit a proposal for performance of the work as specified in the statement of work. Such proposals may be considered if overall performance would be improved or not compromised and if they are in the best interests of the Government. Alternative proposals, or deviations from any requirements of this RFP, shall be clearly identified. (6) **Evaluation of Proposals** The Government will evaluate technical proposals in accordance with the criteria set forth in PART IV, SECTION M of this RFP.
Item 24:	*If this item is applicable, SECTION L.11. of the specific RFP shall so state.* (7) **Potential Award Without Discussions** The Government reserves the right to award a contract without discussions if the Contracting Officer determines that the initial prices are fair and reasonable and that discussions are not necessary.
Item 25:	*This item is applicable to all RFPs.* **Use of the Metric System of Measurement** (8) It is the policy of the Department of Health and Human Services to support the Federal transition to the metric system and to use the metric system of measurement in all procurements, grants, and other business related activities unless such use is impracticable or is likely to cause significant inefficiencies. The offeror is encouraged to prepare their proposal using either "Hard Metric," "Soft Metric," or "Dual Systems" of measurement. The following definitions are provided for your information: **Hard Metric** - The replacement of a standard inch-pound size with an accepted metric size for a particular purpose. An example of size substitution might be: selling or packaging liquids by the liter instead of by the pint or quart (as for soft drinks), or instead of by the gallon (as for gasoline). **Soft Metric** - The result of a mathematical conversion of inch-pound measurements to metric equivalents for a particular purpose. The physical characteristics are not changed. **Dual Systems** - The use of both inch-pound and metric systems. For example, an item is designed, produced, and described in inch-pound values with soft metric values also shown for information or comparison purposes.
Item 26:	*The following item is applicable to all offerors that are considered under the Privacy Rule to be "Covered Entities" (as defined in the Health Insurance Portability and Accountability Act of 1996 ("HIPAA").* (9) **Standards for Privacy of Individually Identifiable Health Information** The Department of Health and Human Services (DHHS) issued final modifications to the "Standards for Privacy of Individually Identifiable Health Information," the "Privacy Rule," on August 14, 2002. The Privacy Rule is a federal regulation under the Health Insurance Portability and Accountability Act (HIPAA) of 1996 that governs the protection of individually identifiable health information and is administered and enforced by the DHHS Office for Civil Rights (OCR). Those who must comply with the Privacy Rule (classified under the Rule as "covered entities" must do so by April 14, 2003 (with the exception of small health plans which have an extra year to comply. Decisions about the applicability and implementation of the Privacy Rule reside with the contractor and his/her institution. The OCR Web site (http://www.hhs.gov/ocr/) provides information of the Privacy Rule, including a complete Regulation Text and a set of decision tools on "Am I a covered entity?" Information on the impact of the HIPAA Privacy Rule on NIH processes involving the review, award, and administration of grants, cooperative agreements and contracts can be found at: http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-03-025.html.

Item 27:	*The following item is applicable when animals will be involved in the RFP.* (10) **Care of Live Vertebrate Animals** a. The following notice is applicable when contract performance is expected to involve care of live vertebrate animals: **Notice to Offerors of Requirement for Adequate Assurance of Protection of Vertebrate Animal Subjects - (SEPTEMBER 1985)** The Public Health Service (PHS) Policy on Human Care and Use of Laboratory Animals establishes a number of requirements for research activities involving animals. Before a PHS award may be made to an applicant organization, the organization shall file, with the Office of Extramural Research (OER), Office of Laboratory Animal Welfare (OLAW), National Institutes of Health (NIH), PHS, a written Animal Welfare Assurance which commits the organization to comply with the provisions of the PHS Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions, the Animal Welfare Act, and the Guide for the Care and Use of Laboratory Animals prepared by the Institute of Laboratory Animal Resources. In accordance with the PHS Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions, applicant organizations must establish a committee, qualified through the experience and expertise of its members, to oversee the institution's animal program, facilities and procedures. No PHS award involving the use of animals shall be made unless the Animal Welfare Assurance has been approved by OER. Prior to award, the Contracting Officer will notify Contractor(s) selected for projects that involve live vertebrate animals that an Animal Welfare Assurance is required. The Contracting Officer will request that OER, OLAW negotiate an acceptable Animal Welfare Assurance with those Contractor(s). For further information, OER, OLAW, may be contacted at Rockledge Center I - Suite 1050, 6705 Rockledge Drive, Bethesda, MD 20817, (301) 496-7163, ext 234. FAX copies are of the PHS Policy are available at (301) 402-2803. This policy is also available on the Internet at http://www.grants.nih.gov/grants/olaw/olaw.htm. b. The following information must be included in the offeror's technical proposal: - identification of the species and approximate number of animals to be used; - rationale for involving animals, and for the appropriateness of the species and numbers used; - a complete description of the proposed use of the animals; - a description of procedures designed to assure that discomfort and injury to animals will be limited to that which is unavoidable in the conduct of scientifically valuable research, and that analgesic, anesthetic, and tranquilizing drugs will be used where indicated and appropriate to minimize discomfort and pain to animals; and - a description of any euthanasia method to be used. c. If an Animal Assurance is already in place, the offeror's proposal shall include: -The Animal Welfare Assurance number. -The date last certified by OLAW. (i.e. assurance letter from OLAW) -Evidence of recent AAALAC Accreditation, if required by the Statement of Work of the specific RFP.
Item 28:	*The following item is applicable when contract performance will involve possession, use, or transfer of select biological agents or toxins.* (11) **Possession, Use and Transfer of Select Biological Agents or Toxins** The following notice is applicable when contract performance is expected to involve possession, use and/or transfer of select biological agents or toxins: **Notice to Offerors of Requirements of: 42 CFR Part 73, Select Agents and Toxins** (relating to public health and safety)**; Agricultural Bioterrorism Protection Act of 2002,** which consists of **7 CFR Part 331, Possession, Use, and Transfer of Biological Agents and Toxins** (relating to plant health or plant products)**; and 9 CFR Part 121, Possession, Use, and Transfer of Biological Agents and Toxins** (relating to human and animal health, animal health or animal products) - **December 13, 2002**

	For prime or subcontract awards to domestic institutions who possess, use, and/or transfer Select Agents under this contract, the institution must complete registration with the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (DHHS) or the Animal and Plant Health Inspection Services (APHIS), U.S. Department of Agriculture (USDA), as applicable, before using NIH funds for research involving Select Agents. No NIH funds can be used for research involving Select Agents if the final registration certificate is denied. For prime or subcontract awards to foreign institutions who possess, use, and/or transfer Select Agents under this contract, the institution must provide information satisfactory to the NIH that a process equivalent to that described in 42 CFR 73 (http://www.cdc.gov/od/sap/docs/42cfr73.pdf) for U.S. institutions is in place and will be administered on behalf of all Select Agent work sponsored by these funds before using these funds for any work directly involving the Select Agents. In the technical proposal, the offeror must include details about the select agent and the quantity proposed to be used during contract performance. When requested by the contracting officer during negotiations, potential awardees must provide information addressing the following key elements for the foreign institutions: safety, security, training, procedures for ensuring that only approved/appropriate individuals have access to the Select Agents, and any applicable laws, regulations and policies equivalent to 42 CFR 73. An NIAID-chaired committee of U.S. federal employees (including representatives of NIH grants/contracts and scientific program management, CDC , Department of Justice and other federal intelligence agencies, and Department of State) will assess the policies and procedures for comparability to the U.S. requirements described in 42 CFR Part 73. Toward this end, when requested during negotiations, potential awardees will be asked to provide key information delineating any laws, regulations, policies, and procedures applicable to the foreign institution for the safe and secure possession, use, and transfer of Select Agents. This includes concise summaries of safety, security, and training plans, and applicable laws, regulations, and policies. For the purpose of security risk assessments, foreign institutions must provide the names of all individuals who will have access to the Select Agents and procedures for ensuring that only approved and appropriate individuals have access to Select Agents under the resulting contract. If the proposed contract work will not involve Select Agents, the offeror must include a statement in their technical proposal that the proposed work does not now nor will it in the future (i.e. throughout the life of the award) involve Select Agents. Listings of HHS Select Agents and Toxins, biologic agents and toxins, and Overlap agents or toxins as well as information about the registration process, can be obtained on the Select Agent Program Web site at http://www.cdc.gov/od/sap/.
Item 29:	*This item is applicable to all Research and Development RFPs.* (12) **Obtaining and Disseminating Biomedical Research Resources** As a public sponsor of biomedical research, the National Institutes of Health (NIH) has a dual interest in accelerating scientific discovery and facilitating product development. Intellectual property restrictions can stifle the broad dissemination of new discoveries and limit future avenues of research and product development. At the same time, reasonable restrictions on the dissemination of research tools are sometimes necessary to protect legitimate proprietary interests and to preserve incentives for commercial development. To assist NIH contractors achieve an appropriate balance, the NIH has provided guidance in the form of a two-part document, consisting of Principles setting forth the fundamental concepts and Guidelines that provide specific information to patent and license professionals and sponsored research administrators for implementation. The purpose of these Principles and Guidelines is to assist NIH funding recipients in determining: 1) Reasonable terms and conditions for making NIH-funded research resources available to scientists in other institutions in the public and private sectors (disseminating research tools); and 2) Restrictions to accept as a conditions of receiving access to research tools for use in NIH-funded research (acquiring research tools). The intent is to help recipients ensure that the conditions they impose and accept on the transfer of research tools will facilitate further biomedical research, consistent with the requirements of the Bayh-Dole Act and NIH funding policy. This policy, entitled, "Sharing Biomedical Research Resources: Principles and Guidelines for Recipients of NIH Research Grants and Contracts," (Federal Register Notice, December 23, 1999 [64 FR 72090] will be included in any contract awarded from this solicitation. It can be found at the following website: http://ott.od.nih.gov/NewPages/64FR72090.pdf.

Item 30:	*If this item is applicable, SECTION L.II. of the specific RFP shall so state.* (a) **Sharing Research Data** The NIH endorses the sharing of final research data to expedite the translation of research results into knowledge, products, and procedures to improve human health. This contract is expected to generate research data. Therefore, the offeror must submit a plan for data sharing or state why data sharing is not possible. If data sharing is limited, the offeror should explain such limitations in its data sharing plan. NIH's data sharing policy may be found at the following Web site: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html **Note to Offeror: If this RFP is for a Multi-Center Clinical Trial or Epidemiological Study, the following paragraph will also apply.* If the resultant contract is part of a collaborative program involving multiple sites, the data sharing will be governed by a dissemination plan to be developed jointly following award. Offerors must include in their proposals a statement of willingness to work collaboratively after award with the other funded sites to prepare a joint dissemination plan. Coordinating Center proposals should describe methods to coordinate the dissemination planning and implementation. The Coordinating Center must include a budget and justification for any additional costs of this collaborative effort.
Item 31:	*If this item is applicable, SECTION L.II. of the specific RFP shall so state.* (b) **Sharing of Model Organisms for Biomedical Research** The NIH Research Tools Policy, also referred to as Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources: Final Notice, December 1999, supports the concept of timely sharing and distribution of research resources. In accordance with NIH Guide Notice NOT-OD-04-042, dated May 7, 2004, the NIH provides further sharing guidance with particular attention on model organisms for biomedical research. Such organisms include, but are not limited to: mammalian models such as the mouse and rat, and non-mammalian models, such as budding yeast, social amoebae, round worm, fruit fly, zebra fish, and frog. Research resources to be shared include genetically modified or mutant organisms, sperm, embryos, protocols for genetic and phenotypic screens, mutagenesis protocols, and genetic and phenotypic data for all mutant strains. Offerors must include in their proposal a description of a specific plan for sharing and distributing unique model organism research resources generated using NIH funding so that other researchers can benefit from these resources, OR provide appropriate reasons why such sharing is restricted or not possible. A reasonable time frame for periodic disposition of material and associated data must be specified in the proposal. In addition, the plan must address if, or how, offerors will exercise their intellectual property rights while making model organisms and research resources available to the broader scientific community. At a minimum, the plan should address the following: - Will material transfers be made with no more restrictive terms than in a Simple Letter Agreement (SLA) (http://ott.od.nih.gov/NewPages/Rtguide_final.html#sla)for the transfer of materials or the Uniform Biological Material Transfer Agreement (UBMTA) (http://ott/od/nh/gov/NewPages/UMTA.pdf)? - How will inappropriate “reach-through” requirements (as discussed in the NIH Research Tools Policy) on materials transferred be discussed? - How will technologies remain widely available and accessible to the research community, for example, if any intellectual property rights arise for which a patent application may be filed? Offerors may request funds in their cost proposal to defray reasonable costs associated with sharing materials or data or transfer of model organisms and associated data to appropriate repositories.

Item 32:	*If this item is applicable, SECTION L.II. of the specific RFP shall so state.* (13) **Specific Copyright Provisions Applicable to Software Development and/or Enhancements** Under the provisions of the Rights in Data General clause (52.227-14), contractors must seek permission to establish a copyright for software and associated data generated under a contract. As a general rule, permission is normally granted provided, a paid-up, world-wide, irrevocable, nonexclusive license to the government is provided. This is to advise offerors that for this project, the government intends to assert additional copyright permissions under this contract.
Item 33:	*This item is applicable to all RFPs.* (14) **Privacy Act - Treatment of Proposal Information** The Privacy Act of 1974 (P.L. 93-579) requires that a Federal agency advise each individual whom it asks to supply information, the authority which authorizes the solicitation, whether disclosure is voluntary or mandatory, the principal purpose or purposes for which the information is intended to be used, the uses outside the agency which may be made of the information, and the effects on the individual, if any, of not providing all or any part of the requested information. The NIH is requesting the information called for in this RFP pursuant to the authority provided by Sec. 301(a)(7) of the Public Health Service Act, as amended, and P.L. 92-218, as amended. Providing the information requested is entirely voluntary. The collection of this information is for the purpose of conducting an accurate, fair, and adequate review prior to a discussion as to whether to award a contract. Failure to provide any or all of the requested information may result in a less than adequate review. In addition, the Privacy Act of 1974 (P.L. 93-579, Section 7) requires that the following information be provided when individuals are requested to disclose their social security number. Provision of the social security number is voluntary. Social security numbers are requested for the purpose of accurate and efficient identification, referral, review and management of NIH contracting programs. Authority for requesting this information is provided by Section 301 and Title IV of the PHS Act, as amended. The information provided by you may be routinely disclosed for the following purposes: -to the cognizant audit agency and the General Accounting Office for auditing. -to the Department of Justice as required for litigation. -to respond to congressional inquiries. -to qualified experts, not within the definition of Department employees, for opinions as a part of the review process. (15) **Selection of Offerors** a. For research contracts and contracts for which the technical proposal is considered of paramount importance in the contract award determination, the acceptability of the scientific or technical portion of each proposal will be evaluated by a technical review committee. The committee will evaluate each proposal in strict conformity with the evaluation criteria of the RFP, utilizing point scores and written critiques. The committee may suggest that the Contracting Officer request clarifying information from an offeror. b. The business portion of each contract proposal will be subjected to a cost and price analysis, management analysis, etc. c. If award will be made without conducting discussions, offerors may be given the opportunity to clarify certain aspects of their proposal (e.g., the relevance of an offeror's past performance information and adverse past performance information to which the offeror has not previously had an opportunity to respond) or to resolve minor or clerical errors. d. If the Government intends to conduct discussions prior to awarding a contract-

1) Communications will be held with offerors whose past performance information is the determining factor preventing them from being placed within the competitive range. Such communications shall address adverse past performance information to which an offeror has not had a prior opportunity to respond. Also, communications may be held with any other offerors whose exclusion from, or inclusion in, the competitive range is uncertain.

Such communications shall not be used to cure proposal deficiencies or omissions that alter the technical or cost elements of the proposal, and/or otherwise revise the proposal, but may be considered in rating proposals for the purpose of establishing the competitive range.

2) The Contracting Officer will, in concert with program staff, decide which proposals are in the competitive range. The competitive range will be comprised of all of the most highly rated proposals. Oral or written discussions will be conducted with all offerors in the competitive range.

While it is NCI's policy to conduct discussions with all offerors in the competitive range, NCI reserves the right, in special circumstances, to limit the number of proposals included in the competitive range to the greatest number that will permit an efficient competition. All aspects of the proposals are subject to discussions, including cost, technical approach, past performance, and contractual terms and conditions. At the conclusion of discussions, each offeror still in the competitive range shall be given an opportunity to submit a written Final Proposal Revision (FPR) with the reservation of the right to conduct finalization of details with the selected source in accordance with HHSAR 315.370.

e. The process described in FAR 15.101-1 will be employed, which permits the Government to make tradeoffs among cost or price and non-cost factors and to consider award to other than the lowest price offeror or other than the highest technically rated offeror. This process will take into consideration the results of the technical evaluation, the past performance evaluation (if applicable) and the cost analysis.

f. The NCI reserves the right to make a single award, multiple awards, or no award at all to the RFP. In addition, the RFP may be amended or canceled as necessary to meet NCI requirements. Synopses of awards exceeding $25,000 will be published in FedBizOpps.

Item 34:

The following item is applicable to all RFPs that are expected to exceed $500,000. If applicable, SECTION L.II. of the specific RFP shall identify anticipated subcontracting plan goals for the project. See the last paragraph of this item.

(16) **Small Business Subcontracting Plan**

If the proposed contract exceeds a total estimated cost of $500,000 for the entire period of performance, the apparent successful offeror shall be required to submit an acceptable subcontracting plan in accordance with the terms of the clause entitled "Small Business Subcontracting Plan," FAR Clause No. 52.219-9, incorporated herein by reference in the Solicitation, Attachment to this RFP is an example of such a plan.

a) THIS PROVISION DOES NOT APPLY TO SMALL BUSINESS CONCERNS.

b) The term "subcontract" means any agreement (other than one involving an employer-employee relationship) entered into by a Federal Government prime contractor or subcontractor calling for supplies or services required for the performance of the original contract or subcontract. This includes, but is not limited to, agreements/purchase orders for supplies and services such as equipment purchase, copying services, and travel services.

c) The offeror understands that:

(1) No contract will be awarded unless and until an acceptable plan is negotiated with the Contracting Officer which plan will be incorporated into the contract, as a material part thereof.

(2) An acceptable plan must, in the determination of the Contracting Officer, provide the maximum practicable opportunity for Small Businesses, Small Disadvantaged Businesses, Women-Owned Small businesses, HubZone Small Businesses, Veteran-Owned Small

Businesses, and Service Disabled Veteran-Owned Small Businesses to participate in the performance of the contract.

(3) If a subcontracting plan acceptable to the Contracting Officer is not negotiated within the time limits prescribed by the contracting activity and such failure arises out of causes within the control and with the fault or negligence of the offeror, the offeror shall be ineligible for an award. The Contracting Officer shall notify the Contractor in writing of the reasons for determining a subcontracting plan unacceptable early enough in the negotiation process to allow the Contractor to modify the plan within the time limits prescribed.

(4) Prior compliance of the offeror with other such subcontracting plans under previous contracts will be considered by the Contracting Officer in determining the responsibility of the offeror for award of the contract.

(5) It is the offeror's responsibility to develop a satisfactory subcontracting plan with respect to Small Business Concerns, Small Disadvantaged Business Concerns, Women-Owned Small Business Concerns, HubZone Small Business Concerns, Veteran-Owned Small Business Concerns, and Service Disabled Veteran-Owned Small Business Concerns that each such aspect of the offeror's plan will be judged independent of the other.

(6) The offeror will submit, as required by the Contracting Officer, subcontracting reports in accordance with the instructions thereon, and as further directed by the Contracting Officer. Subcontractors will also submit these reports to the Government's Contracting Officer or as otherwise directed, with a copy to the prime Contractor's designated small and disadvantaged business liaison.

d) Each plan must contain the following:

(1) Goals, expressed in terms of percentages of total planned subcontracting dollars, for the use of Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Business Concerns as subcontractors.

(2) A statement of total dollars planned to be subcontracted. A statement of total dollars to be subcontracted to each of the following type of small business concerns: Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses.

(3) A description of the principal types of supplies and services to be subcontracted with an identification of which supplies and services are expected to be subcontracted to Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and/or Service Disabled Veteran-Owned Small Business Concerns.

(4) A description of the method used to develop the subcontracting goals.

(5) A description of the method used to identify potential sources for solicitation purposes.

(6) A statement as to whether or not indirect costs were included in establishing subcontracting goals. If they were, a description of the method used to determine the proportionate share of indirect costs to be incurred with Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses.

(7) The name of the individual employed by the offeror who will administer the offeror's subcontracting program and a description of his/her duties.

(8) A description of the efforts the offeror will make to assure that Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses have an equitable chance to compete for subcontracts.

(9) Assurances that the offeror will include in all subcontracts the contract clause "Utilization of Small Business Concerns." Assure that all subcontractors, other than small businesses, in excess of $500,000 adopt a plan similar to the plan agreed upon by the offeror.

(10) Assurances that the offeror (and any required subcontractors) will cooperate in studies or surveys as required and submit required reports (SF 294 and SF 295) to the Government.

(11) List the types of records the offeror will maintain to demonstrate procedures that have been adopted to comply with the requirement and goals in the plan, including establishing source lists. Also, the offeror shall describe its efforts to locate Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses and award subcontracts to them.

For additional information about each of the above elements required to be contained the subcontracting plan, see FAR Clause 52.219-9, Small Business Subcontracting Plan, and the Sample Subcontracting Plan which is provided as an attachment to this RFP in SECTION J.

HHS expects each procuring activity to establish minimum subcontracting goals for all procurements. The anticipated minimum goals for this RFP are as follows:

Note to Offeror: The anticipated goals for each applicable RFP shall be identified in SECTION L.II. of the specific RFP.

___% for Small Business; ___% for Small Disadvantaged Business; ___% for Women-Owned Small Business; ___% for HUBZone Small Business; and ___% for Veteran-Owned Small Business and Service-Disabled Veteran-Owned Small Business.

Item 35:

The following item is applicable to all competitive RFPs expected to exceed $100,000.

(17) **HUBZone Small Business Concerns**

Small Business offerors located in underutilized business zones, called "HUBZones," will be evaluated in accordance with FAR Clause 52.219-4, NOTICE OF PRICE EVALUATION PREFERENCE FOR HUBZONE SMALL BUSINESS CONCERNS, which is incorporated by reference in ARTICLE I.3. of this solicitation. Qualified HUBZone firms are identified in the Small Business Administration website at http://www.sba.gov/hubzone.

Item 36:

If this item is applicable, SECTION L.II. of the specific RFP shall so state.

(18) **Extent of Small Disadvantaged Business Participation**

In accordance with FAR Subpart 15.304(c)(4), the extent of participation of Small Disadvantaged Business (SDB) concerns in performance of the contract in the authorized NAICS Subsectors shall be evaluated in unrestricted competitive acquisitions expected to exceed $500,000 ($1,000,000 for construction) subject to certain limitations (see FAR 19.1202-1 and 19.1202-2(b). The dollar amounts cited above include any option years/option quantities that may be included in this solicitation. The definition of a "small disadvantaged business" is cited in FAR 19.001.

The factor entitled “Extent of Small Disadvantaged Business Participation” as set forth under the Evaluation Criteria in Section M shall be used for evaluation purposes. Credit under this evaluation factor is not available to SDB concerns that receive a Price Evaluation Adjustment (PEA) under FAR 19.11. Therefore, an SDB will be evaluated on this factor only if that SDB concern waives the PEA. **Waiver of the price evaluation adjustment shall be clearly stated in the proposal.**

The Department of Commerce determines, on an annual basis, by Subsectors, as contained in the North American Industry Classification System (NAICS) code, and region, if any, the authorized SDB procurement mechanisms and applicable factors (percentages). The NAICS codes can be found at:

http://www.sba.gov/size/

The Department of Commerce website for the annual determination is:

http://www.arnet.gov/References/sdbadjustments.htm

Offerors shall include with their offers, SDB targets, expressed as dollars and percentages of total contract value, in each of the applicable, authorized NAICS Subsector(s). The applicable authorized NAICS Subsector(s) for this project is (are) identified elsewhere in this RFP. A total target for SDB participation by the prime contractor, that includes any joint ventures and team members, shall be

provided as well as a total target for SDB participation by subcontractors. In addition, offerors must provide information that describes their plans for meeting the targets set forth in their proposal. **This information shall be provided in one clearly marked section of the Business Proposal, which shall describe the extent of participation of SDB concerns in the performance of the contract.**

If the evaluation factor in this solicitation includes an SDB evaluation factor or subfactor that considers the extent to which SDB concerns are specifically identified, the SDB concerns considered in the evaluation shall be listed in any resultant contract. Offerors should note that addressing the extent of small disadvantaged business participation **is not in any way intended to be a substitute** for submission of the subcontracting plan, if it is required by this solicitation. An example of the type of information that might be given (in addition to the narrative describing the plan for meeting the targets) follows:

EXAMPLE

Targets for SDB Participation - NAICS Subsector 223

	SDB Percentage of Total Contract Value	**SDB Dollars**
Total Contract Value- $1,000,000	25%	$250,000
SDB Participation by Prime	10%	$100,000
(Includes joint venture partners and team arrangements)*		
SDB Participation by subcontractors	15%	$150,000

*Note: FAR Subpart 9.6 defines "Contractor team arrangements" to include two or more companies forming a partnership or joint venture to act as a potential prime contractor, or a potential prime contractor who agrees with one or more companies to have them act as its subcontractors on a specific contract or acquisition program. For purposes of evaluation of the SDB participation factor, FAR 19.1202-4 requires that SDB joint ventures and teaming arrangements at the prime level be presented separately from SDB participation by subcontractors.

Item 37: *The following item is applicable to commercial organizations.*

(19) **Reimbursement of Costs for Independent Research and Development Projects (Commercial Organizations Only)**

The primary purpose of the Public Health Service (PHS) is to support and advance independent research within the scientific community. PHS has established effective, time tested and well recognized and accepted procedures for stimulating and supporting this independent research by selecting from multitudes of proposals those research projects most worthy of support within the constraints of its appropriations. The reimbursement of independent research and development costs not incidental to product improvement, through the indirect cost mechanism, would circumvent this competitive process.

To ensure that all research and development projects receive similar and equal consideration, all offerors may compete for direct funding for independent research and development projects they consider worthy of support by submitting those projects to the appropriate Public Health Service grant and/or contract office for review. Since these projects may be submitted for direct funding, the successful offeror agrees that no costs for any independent research and development project, including applicable indirect costs, will be claimed under any contract resulting from this solicitation.

Item 38: *If this item is applicable, SECTION L.II. of the specific RFP shall so state.*

(20) **Salary Rate Limitation in Fiscal Year 2004**

Offerors are advised that pursuant to P.L. 108-199, no NIH Fiscal Year 2004 (October 1, 2003 - September 30, 2004) funds may be used to pay the direct annual salary of an individual through any contract awarded as a result of this solicitation at a rate in excess of the Executive Schedule, Level I (direct salary is exclusive of Overhead, Fringe Benefits and General and Administrative expenses,

	also referred to as "indirect cost" or "facilities and administrative (F&A) costs"). Direct salary has the same meaning as the term "institutional base salary." An individual's direct salary (or institutional base salary) is the annual compensation that the contractor pays for an individual's appointment whether that individual's time is spent on research, teaching, patent care or other activities. Direct salary (or institutional base salary) excludes any income that an individual may be permitted to earn outside of duties to the contractor. This does not preclude the offeror from absorbing that portion of an employee's annual salary (plus the dollar amount for fringe benefits and associated indirect costs) that exceeds a rate of the Executive Schedule, Level I. The salary rate limitation set by P.L. 108-199 applies only to Fiscal Year 2004 funds, however, salary rate ceilings for subsequent years may be included in future DHHS appropriation acts. Multi-year contracts awarded pursuant to this solicitation may be subject to unilateral modifications by the Government if an individual's annual salary exceeds any salary rate ceiling established in future appropriations acts. The Executive Schedule, Level I annual salary rate limit also applies to individuals proposed under subcontracts, however it does not apply to consultants. P.L. 108-199 states in pertinent part: "None of the funds appropriated in this Act for the National Institutes of Health, the Agency for Healthcare Research and Quality, and the Substance Abuse, and Mental Health Services Administration shall be used to pay the salary of an individual through a grant or extramural mechanism at a rate in excess of Executive Level I." Link to Executive Schedule Salaries: http://www.opm.gov/oca/PAYRATES/index.htm ***Note to Offerors:*** *The current Fiscal Year 2004 Executive Level I Salary should be adhered to in the preparation of your proposal. All costs associated with any resultant contract award will be required to be in compliance with the current Fiscal Year 2004 Executive Level I Salary rates.*
Item 39:	*The following Item is applicable to all Research and Development RFPs.* (21) **Institutional Responsibility Regarding Conflicting Interests of Investigators** **EACH INSTITUTION MUST:** (a) Maintain an appropriate written, enforced policy on conflict of interest that complies with 42 CFR Part 50 Subpart F and/or 45 CFR Part 94 as appropriate and inform each investigator of the Institution's policy, the Investigator's reporting responsibilities, and the applicable regulations. If the Institution carries out the NIH funded research through subgrantees, contractors or collaborators, the Institution must take reasonable steps to ensure that Investigators working for such entities comply with the regulations, either by requiring those investigators to comply with the Institution's policy or by requiring the entities to provide assurances to the Institution that will enable the Institution to comply with the regulations. (b) Designate an Institutional official(s) to solicit and review financial disclosure statements from each Investigator who is planning to participate in NIH-funded research. (c) Require that by the time an application/proposal is submitted to the NIH each investigator who is planning to participate in the NIH-funded research has submitted to the designated official(s) a listing of his/her known Significant Financial Interests (and those of his/her spouse and dependent children): (i) that would reasonably appear to be affected by the research for which the NIH funding is sought; and (ii) in entities whose financial interests would reasonably appear to be affected by the research. All financial disclosures must be updated during the period of the award, either on an annual basis or as new reportable Significant Financial Interests are obtained. (d) Provide guidelines consistent with the regulations for the designated official(s) to identify conflicting interests and take such actions as necessary to ensure that such conflicting interests will be managed, reduced, or eliminated. (e) Maintain records, identifiable to each award, of all financial disclosures and all actions taken by the institution with respect to each conflicting interest for: (1) in the case of grants, at least three years from the date of submission of the final expenditures report or, where applicable, from other dates specified in 45 CFR Part 74.53(b) and (2) in the case of contracts, 3 years after final payment or, where applicable, for the other time period specified in 48 CFR Part 4

	Subpart 4.7, Contract Records Retention. (f) Establish adequate enforcement mechanisms and provide for sanctions where appropriate. (g) Certify, in each application/proposal for funding to which the regulations applies, that: 1) there is in effect at the Institution a written and enforced administrative process to identify and manage, reduce or eliminate conflicting interests with respect to all research projects for which funding is sought from the NIH; 2) prior to the Institution's expenditure of any funds under the award, the Institution will report to the awarding component the existence of a conflicting interest (but not the nature of the interest or other details) found by the Institution and assure that the interest has been managed, reduced or eliminated in accord with the regulations; and for any interest that the Institution identifies as conflicting subsequent to the expenditure of funds after award, the report will be made and the conflicting interest managed, reduced, or eliminated, at least on a temporary basis within sixty days of that identification; 3) the Institution agrees to make information available, upon request, to the awarding component regarding all conflicting interests identified by the Institution and how those interested have been managed, reduced, or eliminated to protect the research from bias; and 4) the Institution will otherwise comply with the regulations. **Institutional Management of Conflicting Interests** (a) The designated official(s) must: (1) review all financial disclosures; and (2) determine whether conflict of interest exists, and if so, determine what actions should be taken by the Institution to manage, reduce or eliminate such conflict of interest. **A conflict of interest exists when the designated official(s) reasonably determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the NIH-funded research**. Examples of conditions or restrictions that might be imposed to manage actual or potential conflicts of interests include, but are not limited to: (i) public disclosure of significant financial interests; (ii) monitoring of research by independent reviewers; (iii) modification of the research plan; (iv) disqualification of the Investigator(s) from participation in all or a portion of the research funded by the awarding component; (v) divestiture of significant financial interests; or (vi) severance of relationships that create actual or potential conflicts of interests. (b) An Institution may require the management of other conflicting financial interests in addition to those described in paragraph (a) of this section, as the Institution deems appropriate.
Item 40:	*The following item is applicable to Educational Institutions.* (22) **ROTC Access and Federal Military Recruiting on Campus** Section 514 of the FY 1997 Appropriations Act prohibits NIH from providing contract funds to educational institutions that the Secretary of Defense determines have a policy or practice (regardless of when implemented) that either prohibits, or in effect prevents (1) the maintaining, establishing, or operation of a unit of the Senior Reserve Officer Training Corps at the covered education entity; or (2) a student at the covered educational entity from enrolling in a unit of the Senior Reserve Officer Training Corps at another institution of higher education. Further, contract funds may not be provided to educational institutions that have a policy or practice that prohibits or prevents (1) entry to campuses, or access to students (who are 17 years of age or older) on campuses, for purposes of Federal military recruiting; or (2) access by military recruiters for purposes of Federal military recruiting to information pertaining to students (who are 17 years of age or older) enrolled at the covered educational entity.

Item 41:	*If this item is applicable, SECTION L.II. of the specific RFP will identify all pertinent information.* (23) **Past Performance Information** a) Offerors shall submit the following information as part of their [business/technical] proposal. A list of the last *[number will be identified in each RFP]* contracts completed during the past *[one/two/three]* years and *[all contracts/the last contracts awarded]* currently in process that are similar in nature to the solicitation workscope. Contracts listed may include those entered into by the Federal Government, agencies of state and local governments and commercial concerns. Offerors that are newly formed entities without prior contracts should list contracts and subcontracts as required above for all key personnel. Include the following information for each contract or subcontract: 1. Name of Contracting Organization 2. Contract Number (for subcontracts, provide the prime contract number and the subcontract number) 3. Contract Type 4. Total Contract Value 5. Description of Requirement 6. Contracting Officer's Name and Telephone Number 7. Program Manager's Name and Telephone Number 8. Standard Industrial Code The offeror shall submit comparable information on all subcontractors that the offeror proposes to perform a major subcontract under this effort. For the purpose of this solicitation, a "major subcontract" is defined as *[defined in each RFP]*. The offeror may provide information on problems encountered on the identified contracts and the offeror's corrective actions. b) Each offeror will be evaluated on its performance under existing and prior contracts for similar products or services. The Government is not required to contact all references provided by the offeror. Also, references other than those identified by the offeror may be contacted by the Government to obtain additional information that will be used in the evaluation of the offeror's past performance.
Item 42:	*The following item is applicable for RFPs for Construction valued at less than $6,481,000.* (24) **Notice of Buy American Act Requirement--Construction Materials, FAR 52.225-10 (May 2002)** (a) *Definitions*. Construction material, domestic construction material, and foreign construction material, as used in this provision, are defined in the clause of this solicitation entitled "Buy American Act--Construction Materials" (Federal Acquisition Regulation (FAR) clause 52.225-9). (b) *Requests for determinations of inapplicability*. An offeror requesting a determination regarding the inapplicability of the Buy American Act should submit the request to the Contracting Officer in time to allow a determination before submission of offers. The offeror shall include the information and applicable supporting data required by paragraphs (c) and (d) of the clause at FAR 52.225-9 in the request. If an offeror has not requested a determination regarding the inapplicability of the Buy American Act before submitting its offer, or has not received a response to a previous request, the offeror shall include the information and supporting data in the offer. (c) *Evaluation of offers*. (1) The Government will evaluate an offer requesting exception to the requirements of the Buy American Act based on claimed unreasonable cost of domestic construction material, by adding to the offered price the appropriate percentage of the cost of such foreign construction material, as specified in paragraph (b)(3)(i) of the clause at FAR 52.225-9. (2) If evaluation results in a tie between an offeror that requested the substitution of foreign construction material based on unreasonable cost and an offeror that did not request an

	exception, the Contracting Officer will award to the offeror that did not request an exception based on unreasonable cost. (d) *Alternate offers*. (1) When an offer includes foreign construction material not listed by the Government in this solicitation in paragraph (b)(2) of the clause at FAR 52.225-9, the offeror also may submit an alternate offer based on use of equivalent domestic construction material. (2) If an alternate offer is submitted, the offeror shall submit a separate Standard Form 1442 for the alternate offer, and a separate price comparison table prepared in accordance with paragraphs (c) and (d) of the clause at FAR 52.225-9 for the offer that is based on the use of any foreign construction material for which the Government has not yet determined an exception applies. (3) If the Government determines that a particular exception requested in accordance with paragraph (c) of the clause at FAR 52.225-9 does not apply, the Government will evaluate only those offers based on use of the equivalent domestic construction material, and the offeror shall be required to furnish such domestic construction material. An offer based on use of the foreign construction material for which an exception was requested-- (i) Will be rejected as nonresponsive if this acquisition is conducted by sealed bidding; or (ii) May be accepted if revised during negotiations.
Item 43:	*If this item is applicable, SECTION L.11. of the specific RFP shall so state.* **Alternate I (May 2002), FAR 52.225-10**, **Notice of Buy American Act Requirement--Construction Materials (May 2002)**. As prescribed in 25.1102(b)(2), substitute the following paragraph (b) for paragraph (b) of the basic provision: (b) *Requests for determinations of inapplicability*. An offeror requesting a determination regarding the inapplicability of the Buy American Act shall submit the request with its offer, including the information and applicable supporting data required by paragraphs (c) and (d) of the clause at FAR 52.225-9.
Item 44:	*The following item is applicable for RFPs for Construction valued at $6,725,000 or more.* (25) **Notice of Buy American Act Requirement--Construction Materials Under Trade Agreements, FAR 52.225-12 (January 2004)** (a) *Definitions*. Construction material, designated country construction material, domestic construction material, foreign construction material, and FTA country construction material, as used in this provision, are defined in the clause of this solicitation entitled "Buy American Act--Construction Materials under Trade Agreements" (Federal Acquisition Regulation (FAR) clause 52.225-11). (b) *Requests for determination of inapplicability*. An offeror requesting a determination regarding the inapplicability of the Buy American Act should submit the request to the Contracting Officer in time to allow a determination before submission of offers. The offeror shall include the information and applicable supporting data required by paragraphs (c) and (d) of FAR clause 52.225-11 in the request. If an offeror has not requested a determination regarding the inapplicability of the Buy American Act before submitting its offer, or has not received a response to a previous request, the offeror shall include the information and supporting data in the offer. (c) *Evaluation of offers*. (1) The Government will evaluate an offer requesting exception to the requirements of the Buy American Act based on claimed unreasonable cost of domestic construction materials, by adding to the offered price the appropriate percentage of the cost of such foreign construction material, as specified in paragraph (b)(4)(i) of FAR clause 52.225-11. (2) If evaluation results in a tie between an offeror that requested the substitution of foreign construction material based on unreasonable cost and an offeror that did not request an exception, the Contracting Officer will award to the offeror that did not request an

	exception based on unreasonable cost. (d) *Alternate offers*. (1) When an offer includes foreign construction material, other than designated country or FTA country construction material, that is not listed by the Government in this solicitation in paragraph (b)(3) of FAR clause 52.225-11, the offeror also may submit an alternate offer based on use of equivalent domestic, designated country, or FTA country construction material. (2) If an alternate offer is submitted, the offeror shall submit a separate Standard Form 1442 for the alternate offer, and a separate price comparison table prepared in accordance with paragraphs (c) and (d) of FAR clause 52.225-11 for the offer that is based on the use of any foreign construction material for which the Government has not yet determined an exception applies. (3) If the Government determines that a particular exception requested in accordance with paragraph (c) of FAR clause 52.225-11 does not apply, the Government will evaluate only those offers based on use of the equivalent domestic, designated country, or FTA country construction material, and the offeror shall be required to furnish such domestic, designated country, or FTA country construction material. An offer based on use of the foreign construction material for which an exception was requested-- (i) Will be rejected as nonresponsive if this acquisition is conducted by sealed bidding; or (ii) May be accepted if revised during negotiations.
Item 45:	*If this item is applicable, SECTION L.11. of the specific RFP shall so state.* **Alternate I (May 2002), FAR 52.225-12**, **Notice of Buy American Act Requirement--Construction Materials Under Trade Agreements (January 2004)**. As prescribed in 25.1102(d)(2), substitute the following paragraph (b) for paragraph (b) of the basic provision: (b) *Requests for determination of inapplicability*. An offeror requesting a determination regarding the inapplicability of the Buy American Act shall submit the request with its offer, including the information and applicable supporting data required by paragraphs (c) and (d) of FAR clause 52.225-11.
Item 46:	*The following item is applicable for RFPs for Construction valued at $6,725,000 or more, but less than $7,611,532.* **Alternate II (January 2004), FAR 52.225-12, Notice of Buy American Act Requirement-Construction Materials Under Trade Agreements (January 2004).** As prescribed in 25.1102(d)(3), substitute the following paragraphs (a) and (d) for paragraphs (a) and (d) of the basic provision: (a) Definitions. "Chilean construction material," "construction material,'' "designated country construction material,'' "domestic construction material,'' and "foreign construction material,'' as used in this provision, are defined in the clause of this solicitation entitled "Buy American Act--Construction Materials under Trade Agreements'' (Federal Acquisition Regulation (FAR) clause 52.225-11). (d) Alternate offers. (1) When an offer includes foreign construction material, other than designated country or Chilean construction material, that is not listed by the Government in this solicitation in paragraph (b)(3) of FAR clause 52.225-11, the offeror also may submit an alternate offer based on use of equivalent domestic, designated country, or Chilean construction material. (2) If an alternate offer is submitted, the offeror shall submit a separate Standard Form 1442 for the alternate offer, and a separate price comparison table prepared in accordance with paragraphs (c) and (d) of FAR clause 52.225-11 for the offer that is based on the use of any foreign construction material for which the Government has not yet determined an exception applies.

(3) If the Government determines that a particular exception requested in accordance with paragraph (c) of FAR clause 52.225-11 does not apply, the Government will evaluate only those offers based on use of the equivalent domestic, designated country, or Chilean construction material, and the offeror shall be required to furnish such domestic, designated country, or Chilean construction material. An offer based on use of the foreign construction material for which an exception was requested--

(i) Will be rejected as nonresponsive if this acquisition is conducted by sealed bidding; or
(ii) May be accepted if revised during negotiations.

Item 47:

If this item is applicable, SECTION L.II. of the specific RFP shall so state.

(26) **Invitation to Propose Performance-Based Payments, FAR 52.232-28 (March 2000)**

(a) The Government invites the offeror to propose terms under which the Government will make performance-based contract financing payments during contract performance. The Government will consider performance-based payment financing terms proposed by the offeror in the evaluation of the offeror's proposal. The Contracting Officer will incorporate the financing terms of the successful offeror and the FAR clause, Performance-Based Payments, at FAR 52.232-32, in any resulting contract.

(b) In the event of any conflict between the terms proposed by the offeror and the terms in the clause at FAR 52.232-32, Performance-Based Payments, the terms of the clause at FAR 52.232-32 shall govern.

(c) The Contracting Officer will not accept the offeror's proposed performance-based payment financing if the financing does not conform to the following limitations:

(1) The Government will make delivery payments only for supplies delivered and accepted, or services rendered and accepted in accordance with the payment terms of this contract.

(2) The terms and conditions of the performance-based payments must--

(i) Comply with FAR 32.1004;
(ii) Be reasonable and consistent with all other technical and cost information included in the offeror's proposal; and
(iii) Their total shall not exceed 90 percent of the contract price if on a whole contract basis, or 90 percent of the delivery item price if on a delivery item basis.

(3) The terms and conditions of the performance-based financing must be in the best interests of the Government.

(d) The offeror's proposal of performance-based payment financing shall include the following:

(1) The proposed contractual language describing the performance-based payments (see FAR 32.1004 for appropriate criteria for establishing performance bases and performance-based finance payment amounts).

(2) A listing of--

(i) The projected performance-based payment dates and the projected payment amounts; and
(ii) The projected delivery date and the projected payment amount.

(3) Information addressing the Contractor's investment in the contract.

(e) Evaluation of the offeror's proposed prices and financing terms will include whether the offeror's proposed performance-based payment events and payment amounts are reasonable and consistent with all other terms and conditions of the offeror's proposal.

Item 48:	*If this item is applicable, SECTION L.II. of the specific RFP shall so state.* **Alternate I (March 2000), FAR 52.232-28, Invitation to Propose Performance-Based Payments (March 2000).** As prescribed in FAR 32.1005(b)(2), add the following paragraph (f) to the basic provision: (f) The Government will adjust each proposed price to reflect the cost of providing the proposed performance-based payments to determine the total cost to the Government of that particular combination of price and performance-based financing. The Government will make the adjustment using the procedure described in FAR 32.205(c).
Item 49:	*The following item is applicable for all solicitations that will develop, purchase, maintain and/or use Electronic and Information Technology (EIT).* (27) **Electronic and Information Technology Accessibility** Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by P.L.105-220 under Title IV (Rehabilitation Act Amendments of 1998) and the Architectural and Transportation Barriers Compliance Board Electronic and Information Technology (EIT) Accessibility Standards (36 CFR part 1194) require that all EIT acquired must ensure that: a. Federal employees with disabilities have access to and use of information and data that is comparable to the access and use by Federal employees who are not individuals with disabilities; and b. Members of the public with disabilities seeking information or services from an agency have access to and use of information and data that is comparable to the access to and use of information and data by members of the public who are not individuals with disabilities. This requirement includes the development, maintenance, and/or use of EIT products/services, therefore, any proposal submitted in response to this solicitation must demonstrate compliance with the established EIT Accessibility Standards. Further information about Section 508 is available via the Internet at: http://www.section508.gov.
Item 50:	*If this item is applicable, SECTION L.II. of the specific RFP shall so state.* (28) **Prohibition on Contractor Involvement with Terrorist Activities** The contractor acknowledges that U.S. Executive Orders and Laws, including but not limited to E.O. 13224 and P.L. 107-56, prohibit transactions with, and the provision of resources and support to, individuals and organizations associated with terrorism. It is the legal responsibility of the contractor to ensure compliance with these Executive Orders and Laws. This clause must be included in all subcontracts issued under this contract.
Item 51:	*The introductory paragraph below is applicable to all RFPs, however, SECTION L.II. of each RFP shall identify the clauses applicable to the specific requirement* (29) **Solicitation Provisions Incorporated by Reference, FAR 52.252-1 (February 1998)** This Solicitation incorporates one or more solicitation provisions by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. The offeror is cautioned that the listed provisions may include blocks that must be completed by the offeror and submitted with its quotation or offer. In lieu of submitting the full text provisions, the offeror may identify the provision by paragraph identifier and provide the appropriate information with its quotation or offer. Also, the full text of a solicitation provision may be accessed electronically at this address: http://www.arnet.gov/far/.

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1):

- Submission of Offers in the English Language, FAR Clause 52.214-34, (April 1991).
- Submission of Offers in U.S. Currency, FAR Clause 52.214-35, (April 1991).
- Facsimile Proposals, FAR Clause 52.215-5, (October 1997).
- Facilities Capital Cost of Money, FAR Clause 52.215-16, (October 1997).
- Order of Precedence-Uniform Contract Format, FAR Clause 52.215-8, (October 1997).
- Preaward On-Site Equal Opportunity Compliance Evaluation, (Over $10,000,000), FAR Clause 52.222-24, (February 1999).
- Notice of Requirement for Affirmative Action to Ensure Equal Employment Opportunity for Construction, FAR 52.222-23, (February 1999).
- Preparation of Proposals--Construction, FAR Clause 52.236-28, (October 1997).

III. Technical Proposal Instructions

Item 52:

The following item is applicable to all RFPs.

TECHNICAL PROPOSAL INSTRUCTIONS

A detailed work plan must be submitted indicating how each aspect of the statement of work is to be accomplished. Your technical approach should be in as much detail as you consider necessary to fully explain your proposed technical approach or method. The technical proposal should reflect a clear understanding of the nature of the work being undertaken. The technical proposal must include information on how the project is to be organized, staffed, and managed. Information should be provided which will demonstrate your understanding and management of important events or tasks.

(1) **Technical Discussions**

The technical discussion included in the technical proposal should respond to the items set forth below:

Item 53:

If this item is applicable, SECTION L.III. of the specific RFP shall so state.

a) **Project Objectives, NIH-1688-1**

The offeror shall insert a completed NIH Form 1688-1, Project Objective, as provided in Section J, Attachments, behind the Title Page of each copy of the proposal, along with the "Government Notice for Handling Proposals." The NIH Form 1688-1 is to be completed as follows:

- For an **Institution of Higher Education:** The form MUST be completed in its entirety.
- For **OTHER** than an Institution of Higher Education: The starred items (Department, Service, Laboratory or Equivalent, and Major Subdivision) should be left blank.

The information required under the "Summary of Objectives" portion of the form MUST meet the requirements set forth in the section of the form entitled, **"INSTRUCTIONS:"**

Item 54:

The following is applicable to all RFPs.

b) **Statement of Work**

(1) Objectives

State the overall objectives and the specific accomplishments you hope to achieve. Indicate the rationale for your plan, and relation to comparable work in progress elsewhere. Review pertinent work already published which is relevant to this project and your proposed approach. This should support the scope of the project as you perceive it.

(2) Approach

Use as many subparagraphs, appropriately titled, as needed to clearly outline the general plan of work. Discuss phasing of research and, if appropriate, include experimental design and possible or probable outcome of approaches proposed.

(3) Methods

Describe in detail the methodologies you will use for the project, indicating your level of experience with each, areas of anticipated difficulties, and any unusual expenses you anticipate.

(4) Schedule

Provide a schedule for completion of the work and delivery of items specified in the statement of work. Performance or delivery schedules shall be indicated for phases or segments, as applicable, as well as for the overall program. Schedules shall be shown in

terms of calendar months from the date of authorization to proceed or, where applicable, from the date of a stated event, as for example, receipt of a required approval by the Contracting Officer. Unless the request for proposal indicates that the stipulated schedules are mandatory, they shall be treated as desired or recommended schedules. In this event, proposals based upon the offeror's best alternative schedule, involving no overtime, extra shift or other premium, will be accepted for consideration.

c) **Personnel**

Describe the experience and qualifications of personnel who will be assigned for direct work on this program. Information is required which will show the composition of the task or work group, its general qualifications, and recent experience with similar equipment or programs. Special mention shall be made of direct technical supervisors and key technical personnel, and the approximate percentage of the total time each will be available for this program.

OFFERORS SHOULD ASSURE THAT THE PRINCIPAL INVESTIGATOR, AND ALL OTHER PERSONNEL PROPOSED, SHALL NOT BE COMMITTED ON FEDERAL GRANTS AND CONTRACTS FOR MORE THAN A TOTAL OF 100% OF THEIR TIME. IF THE SITUATION ARISES WHERE IT IS DETERMINED THAT A PROPOSED EMPLOYEE IS COMMITTED FOR MORE THAN 100% OF HIS OR HER TIME, THE GOVERNMENT WILL REQUIRE ACTION ON THE PART OF THE OFFEROR TO CORRECT THE TIME COMMITMENT.

(1) Principal Investigator/Project Director

List the name of the Principal Investigator/Project Director responsible for overall implementation of the contract and key contact for technical aspects of the project. Even though there may be co-investigators, identify the Principal Investigator/Project Director who will be responsible for the overall implementation of any awarded contract. Discuss the qualifications, experience, and accomplishments of the Principal Investigator/Project Director. State the estimated time to be spent on the project, his/her proposed duties, and the areas or phases for which he/she will be responsible.

(2) Other Investigators

List all other investigators/professional personnel who will be participating in the project. Discuss the qualifications, experience, and accomplishments. State the estimated time each will spend on the project, proposed duties on the project, and the areas or phases for which each will be responsible.

(3) Additional Personnel

List names, titles, and proposed duties of additional personnel, if any, who will be required for full-time employment, or on a subcontract or consultant basis. The technical areas, character, and extent of subcontract or consultant activity will be indicated and the anticipated sources will be specified and qualified. For all proposed personnel who are not currently members of the offeror's staff, a letter of commitment or other evidence of availability is required. A resume does not meet this requirement. Commitment letters for use of consultants and other personnel to be hired must include:

-The specific items or expertise they will provide.
-Their availability to the project and the amount of time anticipated.
-Willingness to act as a consultant.
-How rights to publications and patents will be handled.

(4) Resumes

Resumes of all key personnel are required. Each must indicate educational background, recent experience, specific or technical accomplishments, and a listing of relevant publications.

(2) **Technical Evaluation**

Proposals will be technically evaluated in accordance with the factors, weights, and order of relative importance as described in the Technical Evaluation Criteria (Section M.__., hereof).

	(3) **Additional Technical Proposal Information** a) Proposals which merely offer to conduct a program in accordance with the requirements of the Government's scope of work will not be eligible for award. The offeror must submit an explanation of the proposed technical approach in conjunction with the tasks to be performed in achieving the project objectives. b) The technical evaluation is conducted in accordance with the weighted technical evaluation criteria by an initial review panel. This evaluation produces a numerical score (points) which is based upon the information contained in the offeror's proposal only. (4) **Other Considerations** Record and discuss specific factors not included elsewhere which support your proposal. Using specifically titled subparagraphs, items may include: a) Any agreements and/or arrangements with subcontractor(s). Provide as much detail as necessary to explain how the statement of work will be accomplished within this working relationship. b) Unique arrangements, equipment, etc., which none or very few organizations are likely to have which is advantageous for effective implementation of this project. c) Equipment and unusual operating procedures established to protect personnel from hazards associated with this project. d) Other factors you feel are important and support your proposed research. e) Recommendations for changing reporting requirements if such changes would be more compatible with the offeror's proposed schedules.
Item 55:	*This item is applicable when Human Subjects will be involved in the RFP. This includes interviews as well as studies and trials.* **IMPORTANT NOTE TO OFFERORS: The following 11 paragraphs [(5) through (15)] shall be addressed in a SEPARATE SECTION of the Technical Proposal entitled, "HUMAN SUBJECTS."** (5) **Human Subjects** The following notice is applicable when contract performance is expected to involve risk to human subjects: **Notice to Offerors of Requirements of 45 CFR Part 46, Protection of Human Subjects (JANUARY 2001)** a) Copies of the Department of Health and Human Services (Department) regulations for the protection of human subjects, 45 CFR Part 46, are available from the Office of Protection from Research Risks (OPRR), National Institutes of Health (NIH), Bethesda, Maryland 20892*****. The regulations provide a systematic means, based on established ethical principles, to safeguard the rights and welfare of individuals who participate as subjects in research activities supported or conducted by the Department. b) The regulations define a human subject as a living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual, or identifiable private information. The regulations extend to the use of human organs, tissue and body fluids from individually identifiable human subjects as well as to graphic, written or recorded information derived from individually identifiable human subjects. The use of autopsy materials is governed by applicable State and local law and is not directly regulated by 45 CFR, Part 46. c) Activities in which the only involvement of human subjects will be in one or more of the categories set forth in 45 CFR 46.101(b)(1-6) are exempt from coverage. d) Inappropriate designations of the noninvolvement of human subjects or of exempt categories

of research in a project may result in delays in the review of a proposal. The National Institutes of Health will make a final determination of whether the proposed activities are covered by the regulations or are in an exempt category, based on the information provided in the proposal. In doubtful cases, prior consideration with OPRR*****, (telephone: 301-496-7014*****), is recommended.

e) In accordance with 45 CFR, Part 46, prospective Contractors being considered for award shall be required to file with OPRR***** an acceptable Assurance of Compliance with the regulations, specifying review procedures and assigning responsibilities for the protection of human subjects. The initial and continuing review of a research project by an institutional review board shall assure that the rights and welfare of the human subjects involved are adequately protected, that the risks to the subjects are reasonable in relation to the potential benefits, if any, to the subjects and the importance of the knowledge to be gained, and that informed consent will be obtained by methods that are adequate and appropriate. Prospective Contractors proposing research that involves human subjects shall be contacted by OPRR***** and given detailed instructions for establishing an institutional review board and filing an Assurance of Compliance.

f) It is recommended that OPRR***** be consulted for advice or guidance concerning either regulatory requirements or ethical issues pertaining to research involving human subjects. (End of Provision)

*******Note: The Office for Human Research Protections (OHRP), Office of the Secretary (OS), Department of Health and Human Services (DHHS) is the office responsible for oversight of the Protection of Human subjects and should replace Office for Protection from Research Risks (OPRR), National Institutes of Health (NIH) wherever it appears in this provision. The phone number to reach this office is 301-496-7005. For more information, the OHRP website may be accessed at http://ohrp.osophs.dhhs.gov/. Copies of the DHHS Regulations for the Protection of Human Subjects, 45 CFR Part 46, are also available on line at http://www.access.gpo.gov/nara/cfr/waisidx_01/45cfr46_01.html.*

(6) **Instructions to Offerors Regarding Protection of Human Subjects**

Note: The requirements in this paragraph (6), may be supplemented when necessary, based on the specific requirements of the solicitation.

Offerors must address the following human subjects protections issues if this contract will be for research involving human subjects (note: under each of the following points below, the offeror should indicate whether the information provided relates to the primary research site, or to a collaborating performance site(s), or to all sites:

(a) Risks to the subjects

Human Subjects Involvement and Characteristics:

- Describe the proposed involvement of human subjects in response to the solicitation.
- Describe the characteristics of the subject population, including their anticipated number, age range, and health status.
- Identify the criteria for inclusion or exclusion of any subpopulation. Explain the rationale for the involvement of special classes of subjects, such as fetuses, pregnant women, children, prisoners, institutionalized individuals, or others who are likely to be vulnerable populations.

Sources of Materials:

- Identify the sources of research material obtained from individually identifiable living human subjects in the form of specimens, records, or data. Indicate whether the material or data will be obtained specifically for research purposes or whether use will be made of existing specimens, records, or data.

Potential Risks:

- Describe the potential risks to subjects (physical, psychological, social, legal, or other) and

assess their likelihood and seriousness to the subjects.

- Describe alternative treatments and procedures, including the risks and benefits of the alternative treatments and procedures, to participants in the proposed research, where appropriate.

(b) Adequacy of Protection Against Risks

Recruitment and Informed Consent:

- Describe plans for the recruitment of subjects and the procedures for obtaining informed consent. Include a description of the circumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects, and the method of documenting consent. The informed consent document for the contractor and any collaborating sites should be submitted only if requested elsewhere in the solicitation. Be aware that an IRB-approved informed consent document for the contractor and any participating collaborative sites must be provided to the Government prior to patient accrual or participant enrollment.

Protection Against Risk:

- Describe the procedures for protecting against or minimizing potential risks, including risks to confidentiality, and assess their likely effectiveness.

- Discuss provisions for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects where appropriate.

- In studies that involve interventions, describe the provisions for data and safety monitoring of the research to ensure the safety of subjects.

(c) Potential Benefits of the Proposed Research to the Subjects and Others

- Discuss the potential benefits of the research to the subjects and others.

- Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to subjects and others.

- Describe treatments and procedures that are alternatives to those provided to the participants by the proposed research, where appropriate.

(d) Importance of the Knowledge to be Gained

- Discuss the importance of the knowledge gained or to be gained as a result of the proposed research.

- Discuss why the risks to subjects are reasonable in relation to the importance of the knowledge that may reasonably be expected to result.

Note: If a test article (investigational new drug, device, or biologic) is involved, name the test article and state whether the 30-day interval between submission of offeror's certification to the Food and Drug Administration (FDA) and its response has elapsed or has been waived and/or whether the FDA has withheld or restricted use of the test article.

Collaborating Site(s)

When research involving human subjects will take place at collaborating site(s) or other performance site(s), the offeror must provide in this section of its proposal a list of the collaborating sites and their assurance numbers. Further, if you are awarded a contract, you must obtain in writing, and keep on file, an assurance from each site that the previous points have been adequately addressed at a level of attention that is at least as high as that documented at your organization. Site(s) added after an award is made must also adhere to the above requirements.

(7) **Required Education in the Protection of Human Research Participants**

NIH policy requires education on the protection of human subject participants for all investigators submitting NIH proposals for contracts for research involving human subjects. This policy announcement is found in the NIH Guide for Grants and Contracts Announcement dated June 5, 2000 at the following website: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html. Offerors should review the policy announcement prior to submission of their offers. The following is a summary of the Policy Announcement:

For any solicitation for research involving human subjects, the offeror shall provide in its technical proposal the following information: (1) a list of the names of the principal investigator and any other individuals proposed under the contract who are responsible for the design and/or conduct of the research; (2) the title of the education program completed (or to be completed prior to the award of the contract) for each named personnel; (3) a one sentence description of the program(s) listed in (2) above. This requirement extends to investigators and all individuals responsible for the design and/or conduct of the research who are working as subcontractors or consultants under the contract.

Curricula that are readily available and meet the educational requirement include the NIH on-line tutorial, titled "Protection of Human Research Subjects: Computer-Based Training for Researchers," available at http://ohsr.od.nih.gov/cbt/. You may download the information at this site at no cost and modify it, if desired. In addition, the University of Rochester has made its training program available for individual investigators. Completion of this program will also satisfy the educational requirement. The University of Rochester manual can be obtained through Centerwatch, Inc. at http://www.centerwatch.com/order/pubs_profs_protect.html. If an institution already has developed educational programs on the protection of research participants, completion of these programs also will satisfy the educational requirement.

In addition, prior to the substitution of the principal investigator or any other individuals responsible for the design and/or conduct of the research under the contract, the contractor shall provide the contracting officer with the title of the education program and a one sentence description of the program that the replacement has completed.

(8) **Inclusion of Women and Minorities in Research Involving Human Subjects**

It is NIH policy that women and members of minority groups and their sub-populations must be included in all NIH-supported clinical research projects involving human subjects, unless a clear and compelling rationale and justification establishes to the satisfaction of the relevant Institute/Center Director that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. The Director, NIH, may determine that exclusion under other circumstances is acceptable, upon the recommendation of an Institute/Center Director, based on a compelling rationale and justification. Cost is not an acceptable reason for exclusion except when the study would duplicate data from other sources. Women of childbearing potential should not be routinely excluded from participation in clinical research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43), ***and applies to research subjects of all ages***.

All investigators proposing research involving human subjects should read the UPDATED "NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research, Amended October 2001," published in the NIH Guide for Grants and Contracts on October 9, 2001 at the following web site:

http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm

These guidelines contain a definition of **clinical research** adopted in June 2001, as: "(1) Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, and (d) development of new technologies; (2) Epidemiologic and behavioral studies; and (3) Outcomes research and health services research" (http://www.nih.gov/news/crp/97report/execsum.htm).

Information Required for ALL Clinical Research Proposals

This solicitation contains a review criterion addressing the adequacy of: (1) the offeror's plans for inclusion of women and minorities in the research proposed; or (2) the offeror's justification(s) for

exclusion of one or both groups from the research proposed.

Provide information on the composition of the proposed study population in terms of sex/gender and racial/ethnic groups and provide a rationale for selection of such subjects in response to the requirements of the solicitation. The description may include (but is not limited to) information on the population characteristics of the disease or condition being studied in the planned research, and/or described in the statement of work, national and local demography, knowledge of the racial/ethnic/cultural characteristics of the population, prior experience and collaborations in recruitment and retention of the populations and subpopulations to be studied, and the plans, arrangements and letters of commitment from relevant community groups and organizations for the planned research.

The proposal must include the following information:

- A description of the subject selection criteria
- The proposed dates of enrollment (beginning and end)
- A description of the proposed outreach programs for recruiting women and minorities as subjects
- A compelling rationale for proposed exclusion of any sex/gender or racial/ethnic group
- The proposed sample composition using the "Targeted/Planned Enrollment Table"(see Section J, Attachments)

NOTE 1: *For all proposals, use the ethnic and racial categories and complete the "Targeted/Planned Enrollment Table in accordance with the Office of Management and Budget (OMB) Directive No. 15, which may be found at: http://www.whitehouse.gov/omb/fedreg/ombdir15.html.*

NOTE 2: *If this is an Indefinite Delivery, Indefinite Quantity (IDIQ) or Requirements contract as defined in FAR 16.5, the proposal should describe in general terms how it will comply with each bulleted item above for each task order. When the Government issues a task order request for proposal, each of the bulleted information items must be fully and specifically addressed in the proposal.*

Standards for Collecting Data. When you, as a contractor, are planning data collection items on race and ethnicity, you shall use, at a minimum, the categories identified in OMB Directive No. 15. The collection of greater detail is encouraged. However, you should design any additional, more detailed items so that they can be aggregated into these required categories. Self-reporting or self-identification using two separate questions is the preferred method for collecting data on race and ethnicity. When you collect race and ethnicity separately, you must collect ethnicity first. You shall offer respondents the option of selecting one or more racial designations. When you collect data on race and ethnicity separately, you shall also make provisions to report the number of respondents in each racial category who are Hispanic or Latino. When you present aggregate data, you shall provide the number of respondents who selected only one category, for each of the five racial categories. If you collapse data on multiple responses, you shall make available, at a minimum, the total number of respondents reporting "more than one race." Federal agencies shall not present data on detailed categories if doing so would compromise data quality or confidentiality standards.

In addition to the above requirements, solicitations for **NIH defined Phase III clinical trials**[1] require that: a) all proposals and/or protocols provide a description of plans to conduct analyses, as appropriate, to detect significant differences in intervention effect (see NIH Guide:

> http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm, Definitions - Significant Difference),

by sex/gender, racial/ethnic groups, and relevant subpopulations, if applicable; and b) all contractors to report annually cumulative subject accrual, and progress in conducting analyses for sex/gender and race/ethnicity differences.

Offerors may obtain copies of the Updated Guidelines from the sources above or from the contact person listed in the solicitation.

Also, the proposal must include one of the following plans:

- Plans to conduct valid analysis to detect significant differences in intervention effect among sex/gender and/or racial/ethnic subgroups when prior studies strongly support these significant differences among subgroups, OR

- Plans to include and analyze sex/gender and/or racial/ethnic subgroups when prior studies strongly support no significant differences in intervention effect between subgroups, OR

- Plans to conduct valid analyses of the intervention effect in sex/gender and/or racial/ethnic subgroups (without requiring high statistical power for each subgroup) when the prior studies neither support nor negate significant differences in intervention effect between subgroups.

Use the form in Section J, Attachments, entitled, "Targeted/Planned Enrollment Table," when preparing your response to the solicitation requirements for inclusion of women and minorities.

Unless otherwise specified in this solicitation, the Government has determined that the work required by this solicitation does not involve a sex/gender specific study or a single or limited number of minority population groups. Therefore, the NIH believes that the inclusion of women and minority populations is appropriate for this project. (See Section M of this RFP for more information about evaluation factors for award.)

Use the format for the Annual Technical Progress Report for Clinical Research Study Populations (See Section J - List of Documents, Exhibits and Other Attachments of the RFP) entitled, "Inclusion Enrollment Report," for reporting in the resultant contract.

[1]See NIH Guide http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm, for the Definition of an "NIH-Defined Phase III clinical trial.

(9) **Inclusion of Children in Research Involving Human Subjects**

It is NIH policy that children (defined below) must be included in all human subjects research, including, but not limited to, clinical trials, conducted under a contract funded by the NIH, unless there are *clear and compelling* reasons not to include them. (See examples of Justifications for Exclusion of Children below). For the purposes of this policy, contracts involving human subjects include categories that would otherwise be exempt from the DHHS Policy for Protection of Human Research Subjects (sections 101(b) and 401(b) of 45 CFR 46), such as surveys, evaluation of educational interventions, and studies of existing data or specimens that should include children as participants. This policy applies to both domestic and foreign research contracts.

For purposes of this policy, a child is defined as an individual under the age of 21 years.

All offerors proposing research involving human subjects should read the "NIH Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects" which was published in the NIH Guide for Grants and Contracts on March 6, 1998 and is available at the following URL address:

http://www.nih.gov/grants/guide/notice-files/not98-024.html

Offerors also may obtain copies from the contact person listed in the RFP.

Inclusion of children as participants in research must be in compliance with all applicable subparts of 45 CFR 46 as well as other pertinent laws and regulations whether or not such research is otherwise exempted from 45 CFR 46. Therefore, any proposals must include a description of plans for including children, unless the offeror presents clear and convincing justification for an exclusion. The "Human Subjects" section of your technical proposal should provide either a description of the plans to include children and a rationale for selecting or excluding a specific age range of child, or an explanation of the reason(s) for excluding children as participants in the research. This solicitation contains a review criterion addressing the adequacy of: (1) the plans for including children as appropriate for the scientific goals of the research; and/or (2) the justification of exclusion of children or exclusion of a specific age range of children.

When children are included, the plan also must include a description of: (1) the expertise of the investigative team for dealing with children at the ages included; (2) the appropriateness of the available facilities to accommodate the children; and, (3) the inclusion of a sufficient number of children to contribute to a meaningful analysis relative to the purpose/objective of the solicitation.

Justifications for Exclusion of Children

It is expected that children will be included in all research involving human subjects unless one or

more of the following exclusionary circumstances can be fully justified:

- The objective of the solicitation is not relevant to children.

- There are laws or regulations barring the inclusion of children in the research to be conducted under the solicitation.

- The knowledge being sought in the research is already available for children or will be obtained from another ongoing study, and an additional study will be redundant. You should provide documentation of other studies justifying the exclusion.

- A separate, age-specific study in children is warranted and preferable. Examples include:

    - The relative rarity of the condition in children, as compared with adults (in that extraordinary effort would be needed to include children); or
    - The number of children is limited because the majority are already accessed by a nationwide pediatric disease research network; or
    - Issues of study design preclude direct applicability of hypotheses and/or interventions to both adults and children (including different cognitive, developmental, or disease stages of different age-related metabolic processes); or
    - Insufficient data are available in adults to judge potential risk in children (in which case one of the research objectives could be to obtain sufficient adult data to make this judgment). While children usually should not be the initial group to be involved in research studies, in some instances, the nature and seriousness of the illness may warrant their participation earlier based on careful risk and benefit analysis; or
    - Study designs aimed at collecting additional data on pre-enrolled adult study subjects (e.g., longitudinal follow-up studies that did not include data on children);
    - Other special cases justified by the offeror and found acceptable to the review group and the Institute Director

Definition of a Child

For the purpose of this solicitation, a child is defined as an individual under the age of 21 years. The definition of child described above will pertain to this solicitation (notwithstanding the FDA definition of a child as an individual from infancy to 16 years of age, and varying definitions employed by some states). Generally, State laws define what constitutes a "child," and such definitions dictate whether or not a person can legally consent to participate in a research study. However, State laws vary, and many do not address when a child can consent to participate in research. Federal Regulations (45 CFR 46, subpart D, Sec.401-409) address DHHS protections for children who participate in research, and rely on State definitions of "child" for consent purposes. Consequently, the children included in this policy (persons under the age of 21) may differ in the age at which their own consent is required and sufficient to participate in research under State law. For example, some states consider a person age 18 to be an adult and therefore one who can provide consent without parental permission.

(10) **Data and Safety Monitoring in Clinical Trials**

Note: The following language may be modified to incorporate an IC's alternate and comparable approach to expressing the NIH policy regarding Data and Safety Monitoring in Clinical Trials.

All offerors are directed to the full text of the NIH Policies regarding Data and Safety Monitoring and Reporting of Adverse Events that are found in the NIH Guide for Grants and Contracts Announcements at the following web sites:

http://grants.nih.gov/grants/guide/notice-files/not98-084.html
http://grants.nih.gov/grants/guide/notice-files/not99-107.html
http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-038.html

All offerors receiving an award under this solicitation must comply with the NIH Policy cited in these NIH Announcements and any other data and safety monitoring requirements found elsewhere in this solicitation.

The following is a brief summary of the Data and Safety Monitoring and Adverse Event Reporting Requirements:

Data and Safety Monitoring is required for every clinical trial. Monitoring must be performed on a regular basis and the conclusions of the monitoring reported to the Project Officer.

The type of data and safety monitoring required will vary based on the type of clinical trial and the potential risks, complexity and nature of the trial. A plan for data and safety monitoring is required for all clinical trials. A general description of a monitoring plan establishes the overall framework for data and safety monitoring. It should describe the entity that will be responsible for the monitoring, and the policies and procedures for adverse event reporting. Phase III clinical trials generally require the establishment of a Data Safety Monitoring Board (DSMB). The establishment of a DSMB is optional for Phase I and Phase II clinical trials.

The DSMB/Plan is established at the time the protocol is developed and must be approved by both the Institutional Review Board (IRB) and the Government and in place before the trial begins. If the protocol will be developed under the contract awarded from this solicitation, a general description of the data and safety monitoring plan must be submitted as part of the proposal and will be reviewed by the scientific review group (Technical Evaluation Panel, (TEP)) convened to evaluate the proposal. If the protocol is developed and is included as part of the submitted proposal, a complete and specific data and safety monitoring plan must be submitted as part of the proposal.

Monitoring Plans, at a minimum, must include the prompt reporting of adverse events to the IRB, the NIH Office of Biotechnology Activities (OBA), and the Food and Drug Administration (FDA). Also, in the plan you should describe the frequency of reporting of the conclusions of the monitoring activities. The overall elements of each plan may vary depending on the size and complexity of the trial. The NIH Policy for Data and Safety Monitoring at http://grants.nih.gov/grants/guide/notice-files/not98-084.html describes examples of monitoring activities to be considered.

The frequency of monitoring will depend upon potential risks, complexity, and the nature of the trial; therefore a number of options for monitoring trials are available. These can include, but are not limited to, monitoring by a:

- Principal Investigator (required)
- Independent individual /Safety Officer
- Designated medical monitor
- Internal Committee or Board with explicit guidelines
- Data and Safety Monitoring Board (DSMB - required for multi-site trials)
- Institutional Review Board (IRB - required)

For multi-site Phase I and Phase II trials, a central reporting entity that will be responsible for preparing timely summary reports of adverse events for distribution among sites and IRBs should be considered.

Organizations with a large number of clinical trials may develop standard monitoring plans for Phase I and Phase II trials. In this case, such organizations may include the IRB-approved monitoring plan as part of the proposal submission.

(11) **Research Involving Human Fetal Tissue**

Human Fetal Tissue means tissue or cells obtained from a dead human fetus, including human embryonic stem cells, human pluripotent stem cells and human embryonic germ cells.

The governing federal statute is the Public Health Service Act, 42 U.S.C. 289g-1 and 289g-2. Implementing regulations and guidance for conducting research on human fetal tissue may be found at 45 CFR 46, Subpart B and http://grants1.nih.gov/grants/guide/notice-files/not93-235.html and any subsequent revisions to this NIH Guide to Grants and Contracts ("Guide") Notice.

By signing the face page of the proposal, the offeror (authorized institutional official) certifies that researchers using human fetal tissue are in compliance with 42 USC 289g-2. This statute specifically prohibits any person from knowingly acquiring, receiving, or transferring any human fetal tissue for valuable consideration. "Valuable consideration" is a concept similar to profit, and does not include reasonable payment for costs associated with the collection processing, preservation, storage, quality control or transportation of these tissues.

Research involving the transplantation of human fetal tissue must be conducted in accordance with applicable Federal, State and local law.

(12) **Research Involving Prisoners as Subjects**

a. HHS Regulations at 45 CFR Part 46, Subpart C provide additional protections pertaining to biomedical and behavioral research involving prisoners or those individuals who, during the period of the contract become prisoners, as subjects. These regulations also set forth the duties of the Institutional Review Board (IRB) where prisoners are involved in the research. HHS-funded research involving prisoners as subjects may not proceed until the Office for Human Research Protections (OHRP) issues approval, in writing, as required by 45 CFR 46.306(a)(2). In addition, OHRP Guidance on the Involvement of Prisoners in Research may be found at: http://ohrp.osophs.dhhs.gov/humansubjects/guidance/prisoner.htm

b. HHS Waiver for Epidemiological Research Involving Prisoners as Subjects

On June 20, 2003 the Secretary of HHS waived the applicability of certain provisions of Subpart C of 45 CFR Part 46, (Additional DHHS Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects) to specific types of epidemiological research involving prisoners as subjects.

The applicability of 45 CFR 46.305(a)(1) and 46.306(a)(2) for certain epidemiological research conducted or funded by DHHS is waived when:

1. The sole purposes are:

   a) to describe the prevalence or incidence of a disease by identifying all cases, or
   b) to study potential risk factor associations for a disease, and

2. The Institution responsible for the conduct of the research certifies to the OHRP that the Institutional Review Board (IRB) approved the research and fulfilled its duties under 45 CFR 46.305(a)(2-7) and determined and documented that:

   a) the research presents no more than minimal risk, and
   b) no more than inconvenience to the prisoner-subjects, and
   c) prisoners are not a particular focus of the research.

For more information about this Waiver see http://ohrp.osophs.dhhs.gov/references/fr06-20.pdf

(13) **Research Involving Recombinant DNA Molecules (including Human Gene Transfer Research)**

Recombinant DNA Molecules are either 1) molecules that are constructed outside of living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell, or 2) DNA molecules that result from the replication of those described in 1).

The NIH Guidelines for Research Involving Recombinant DNA Molecules (http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html and the May 28, 2002 Notice, Compliance with the NIH Guidelines for Research Involving Recombinant DNA Molecules (http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-02-052.html) and any subsequent revisions to the Guide Notice) stipulates biosafety and containment measures for recombinant DNA research and delineates critical, ethical principles and key safety reporting requirements for human gene transfer research (See Appendix M of the NIH Guidelines). These guidelines apply to both basic and clinical research studies.

The Recombinant DNA Advisory Committee (RAC) is charged with the safety of manipulation of genetic material through the use of recombinant DNA techniques. Prior to beginning any clinical trials involving the transfer of recombinant DNA to humans, the trial must be registered with the RAC. If this contract involves new protocols that contain unique and//or novel issues, the RAC must discuss them in a public forum and then the Institutional Biosafety Committee (IBC), the Institutional Review Board (IRB), and the project officer and contracting officer must approve the protocol prior to the start of the research.

Failure to comply with these requirements may result in suspension, limitation, or termination of NIH funding for any work related to Recombinant DNA Research or a requirement for the contracting officer's prior approval of any or all Recombinant DNA projects under any contract awarded from this solicitation. This includes the requirements of the Standing Institutional Biosafety Committee (IBC) (See http://www4.od.nih.gov/oba/IBC/IBCindexpg.htm).

As specified in Appendix M-1-C-4 of the NIH Guidelines, any serious adverse event must be reported immediately to the IRB, the IBC, the Office for Human Research Protections (if applicable), and the NIH Office for Biotechnology Activities (OBA), followed by the filing of a written report with each office/group and copies to the project officer and contracting officer. (http://www4.od.nih.gov/oba/rac/guidelines_02/Appendix_M.htm#_Toc7255836)

(14) **Human Embryonic Germ Cell (HEGC) Research**

1. Guidelines.

Research use of human embryonic germ cells derived from fetal tissue with Federal funds requires review of compliance with the NIH Guidelines for Research Using Human Pluripotent Stem Cells (http://www.nih.gov/news/stemcell/stemcellguidelines.htm) (only the information regarding human embryonic germ cells is relevant). Embryonic germ cells are pluripotent stem cells derived from human embryos. See NIH Guide for Grants and Contracts Notice NOT-OD-02-049, requiring that offerors/contractors submit certain documents to the Human Pluripotent Stem Cell Review Group (HPSCRG), which will be reviewed in a public meeting. Research using human embryonic germ cells may not be performed prior to approval by the HPSCRG.

All offerors should read the "NIH Guidelines" (http://www.nih.gov/news/stemcell/stemcellguidelines.htm) if they either: (1) propose to respond to the Statement of Work requirements by conducting research that uses human embryonic germ cells or, (2) are responding to a Statement of Work that requires the use of human embryonic germ cells.

Offerors may obtain copies of these Guidelines from the website above or from the contact person listed in this solicitation.

Note to Offeror: Below are four (4) subparagraph 2.(s). Each provides information on applicability. If Human Embryonic Stem Cell Research is contemplated, one of the following subparagraphs will apply to your proposal:

*The following subparagraph 2. is applicable if this solicitation is for a SBIR Phase II, a BAA, or a sole source acquisition **AND** the Government specifies in the SOW that human embryonic germ cells shall be used to conduct the required research.*

2. Procedure for Review by Human Pluripotent Stem Cell Review Group (HPSCRG)

The NIH has determined that human embryonic germ cells are required to be used for the conduct of this research. The offeror must submit an original and two copies of the documentation and assurances that address the areas covered the "Procedures for Submission of Compliance Documents to the Human Pluripotent Stem Cell Review Group (HPSCRG) for the Research Use of Human Embryonic Germ Cells" (http://grants2.nih.gov/grants/guide/notice-files/NOT-OD-02-049.html) as a separate attachment in its proposal. Prior to any award made under this solicitation, the documentation and assurances will be subject to review by the HPSCRG, which meets in a public meeting. No research involving the use of human embryonic germ cells may begin prior to HPSCRG approval.

Offerors are encouraged to review issues pertaining to informed consent processes described in Section II.B.2.b of the NIH Guidelines, (http://stemcells.nih.gov/rschFunding/NIHSCguideline2000.pdf). Offerors should also review the March 19, 2002, DHHS Office of Human Research Protection's document titled, "Guidance for Investigators and Institutional Review Boards Regarding Research Involving Human Embryonic Stem Cells, Germ Cells, and Stem Cell-Derived Test Articles," (http://ohrp.osophs.dhhs.gov/humansubjects/guidance/stemcell.pdf)

OR

*The following subparagraph 2. is applicable if this solicitation is for a SBIR Phase II, a BAA, or a sole source acquisition **AND** the Government **DOES NOT** specify in the SOW that human embryonic germ cells shall be used to conduct the required research*

2. Procedure for Review by Human Pluripotent Stem Cell Review Group (HPSCRG)

If, in response to the solicitation, the offeror proposes to use human embryonic germ cells, it must submit, as a separate attachment to its proposal, an original and two copies of the documentation and assurances that address the areas covered in the "Procedures for Submission of Compliance Documents to the Human Pluripotent Stem Cell Review Group (HPSCRG) for the Research Use of Human Embryonic Germ Cells" (http://grants2.nih.gov/grants/guide/notice-files/NOT-OD-02-049.html). Prior to any award made under this solicitation, the documentation and assurances will be subject to review by the HPSCRG, which meets in a public meeting. No research involving the use of human embryonic germ cells may begin prior to HPSCRG approval.

Offerors are encouraged to review issues pertaining to informed consent processes described in Section II.B.2.b of the NIH Guidelines. Offerors should also review the March 19, 2002, DHHS Office of Human Research Protection's document titled "Guidance for Investigators and Institutional Review Boards Regarding Research Involving Human Embryonic Stem Cells, Germ Cells, and Stem Cell-Derived Test Articles," (http://ohrp.osophs.dhhs.gov/humansubjects/guidance/stemcell.pdf)

OR

*The following subparagraph 2. is applicable if this is a competitive solicitation, **IS NOT** a SBIR Phase II, a BAA, or a sole source acquisition **AND** it requires the use of human embryonic germ cells in the conduct of the research.)*

2. Procedure for Review by Human Pluripotent Stem Cell Review Group (HPSCRG)

The NIH has determined that human embryonic germ cells are required to be used for the conduct of this research. The offeror must confirm in its proposal that it plans to use human embryonic germ cells as a part of its research. If the offeror receives a contract award, the contractor may not perform any research using human embryonic germ cells until the Human Pluripotent Stem Cell Review Group (HPSCRG) has reviewed and approved the documentation furnished as prescribed in the "Procedures for Submission of Compliance Documents to the Human Pluripotent Stem Cell Review Group (HPSCRG) for the Research Use of Human Embryonic Germ Cells" (http://grants2.nih.gov/grants/guide/notice-files/NOT-OD-02-049.html) and the contracting officer has notified the contractor of the approval in writing.

Offerors are encouraged to review issues pertaining to informed consent processes described in Section II.B.2.b of the NIH Guidelines (http://stemcells.nih.gov/rschFunding/NIHSCguideline2000.pdf). Offerors should also review the March 19, 2002, DHHS Office of Human Research Protection's document titled "Guidance for Investigators and Institutional Review Boards Regarding Research Involving Human Embryonic Stem Cells, Germ Cells, and Stem Cell-Derived Test Articles," (http://ohrp.osophs.dhhs.gov/humansubjects/guidance/stemcell.pdf)

The resultant contract will be divided into discrete phases or option periods. During Option Period(s)/Phase(s)_____***** of the contract, the contractor shall submit the original and two copies of the required documentation and assurances that address the areas covered in "Procedures for Submission of Compliance Documents to the Human Pluripotent Stem Cell Review Group (HPSCRG) for the Research Use of Human Embryonic Germ Cells" (http://grants2.nih.gov/grants/guide/notice-files/NOT-OD-02-049.html) to the contracting officer. This documentation will be forwarded for review and approval to the HPSCRG.

If the HPSCRG disapproves the documentation presented by the contractor, the contracting officer may elect to either terminate the contract in accordance with the Termination for Convenience clause of the contract OR determine not to exercise subsequent option(s) as appropriate based the terms of the specific contract. Otherwise, when the HPSCRG approves the documentation, the contracting officer will notify the contractor in writing that research using the human embryonic germ cells may commence.

Research involving the use of human embryonic germ cells shall not be conducted under the contract until the HPSCRG review and approval have been obtained, and the contracting officer has provided written notice of such approval to the contractor.

OR

*The following subparagraph 2. is applicable if the solicitation is a competitive solicitation, **IS NOT** a SBIR Phase II, a BAA, or a sole source acquisition; it **DOES NOT REQUIRE** the use of human embryonic germ cells; **HOWEVER**, in response to the Statement of Work Requirements, the offeror may propose to use such human embryonic germ cells, or to conduct the research by using a protocol that derives human embryonic germ cells from fetal tissue.*

2. Procedure for Required Review by Human Pluripotent Stem Cell Review Group (HPSCRG)

If the offeror intends to fulfill the requirements of the Statement of Work by performing research using human embryonic germ cells, it must so state in its proposal.

If the offeror's proposal includes research using human embryonic germ cells and it receives a contract award, the contractor may not perform any research using these human embryonic germ cells until the Human Pluripotent Stem Cell Review Group (HPSCRG) has reviewed and approved the documentation furnished as prescribed in "Procedures for Submission of Compliance Documents to the Human Pluripotent Stem Cell Review Group (HPSCRG) for the Research Use of Human Embryonic Germ Cells" (http://grants2.nih.gov/grants/guide/notice-files/NOT-OD-02-049.html) and the contracting officer has notified the contractor of the approval in writing.

The resultant contract will be divided into discrete phases or option period(s). During Option Period(s)/Phase(s)_____* of the contract, the contractor shall submit the original and two copies of the required documentation and assurances that address the areas covered in "Procedures for Submission of Compliance Documents to the Human Pluripotent Stem Cell Review Group (HPSCRG) for the Research Use of Human Embryonic Germ Cells," (http://grants2.nih.gov/grants/guide/notice-files/NOT-OD-02-049.html) to the contracting officer. This documentation will be forwarded for review and approval to the HPSCRG.

If the HPSCRG disapproves the documentation presented by the contractor, the Contracting Officer may elect to either terminate the contract in accordance with the Termination for Convenience clause of the contract OR determine not to exercise subsequent option(s) as appropriate based the terms of the specific contract. Otherwise, when the HPSCRG approves the documentation, the contracting officer will notify the contractor in writing that research using the human embryonic germ cells may commence.

Research involving the use of human embryonic germ cells shall not be conducted under the contract until the HPSCRG review and approval have been obtained, and the contracting officer has provided written notice of such approval to the contractor.

(15) **Human Embryonic Stem Cell (HESC) Research**

On August 9, 2001, the President announced the criteria that must be met for Federal funds to be used for research on existing human embryonic stem cell lines. These criteria were subsequently published by the NIH at: http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-02-005.html. The following eligibility criteria must be met:

1. The derivation process (which commences with the removal of the inner cell mass from the blastocyst) must have already been initiated prior to August 9, 2001;
2. Prior to August 9, 2001, the embryo from which the stem cell line was derived no longer had the possibility of development as a human being;
3. The stem cells must have been derived from an embryo that was created for reproductive purposes;
4. The embryo was no longer needed for these purposes;
5. Informed consent must have been obtained for the donation of the embryo;
6. No financial inducements were provided for the donation of the embryo.

	To facilitate research using human embryonic stem cells, the NIH has established a Human Embryonic Stem Cell Registry (Athe NIH Registry") that lists the human embryonic stem cells that meet the eligibility criteria. This registry is available at: http://stemcells.nih.gov/registry/. Research involving the derivation of new stem cells from human embryos or the use of human embryonic stem cells that are not listed on the NIH Human Embryonic Stem Cell Registry may not be conducted with Federal funding. If a particular human embryonic stem cell line has not been required by the Statement of Work, an offeror proposing research involving human embryonic stem cells must cite a human embryonic stem cell line that is listed in the NIH Registry in its proposal.
Item 56:	*If this item is applicable, SECTION L.III. of the specific RFP will identify pertinent information.* (5) **Information Technology Systems Security** (a) **Sensitivity and Security Level Designations.** The Statement of Work (SOW) requires the successful offeror to develop or access a Federal Automated Information System (AIS). Based upon the security guidelines contained in the *Department of Health and Human Services (DHHS) Automated Information Systems Security Program (AISSP) Handbook,* the Government has determined that the following apply: (1) Category of Safeguarded Information The category of safeguarded agency information that the successful offeror will develop or access will be identified in the specific RFP. The following lists the possible categories of safeguarded information: **[ ]** Non Sensitive Information **[ ]** Sensitive Information **[ ]** Classified Information: **[ ]** Confidential **[ ]** Secret **[ ]** Top Secret **[ ]** Special Access (2) Security Level Designations The information that the successful offeror will develop or access will be designated in the specific RFP. A separate Security Level Designation will be assigned for: -The **Sensitivity** of the data (Level 1-4). -The **Operational Criticality** of the data (Level 1-4) -The **Overall Security** for the requirement (Level 1-4) (3) Position Sensitivity Designations Prior to award, the Government will determine the position sensitivity designation for each contractor employee that the successful offeror proposes to work under the contract. For proposal preparation purposes, the specific RFP will identify applicable Position Sensitivity Designation(s) from the following: **[ ] Level 6C: Sensitive - High Risk (Requires Suitability Determination with a BI).** Contractor employees assigned to a Level 6C position are subject to a Background Investigation (BI). **[ ] Level 5C: Sensitive - Moderate Risk (Requires Suitability Determination with NACIC).** Contractor employees assigned to a Level 5C position with no previous investigation and approval shall undergo a National Agency Check and Inquiry Investigation plus a Credit Check (NACIC), or possibly a Limited Background Investigation (LBI). **[ ] Level 4C: Classified (Requires Special Access Clearance with an SSBI).** Contractor employees assigned to a Level 4C position are subject to a Single Scope Background Investigation (SSBI).

[ ] Level 3C: Classified (Requires Top Secret Clearance with an SSBI).
Contractor employees assigned to a Level 3C position are subject to a Single Scope Background Investigation (SSBI).

[ ] Level 2C: Classified (Requires Confidential or Secret Clearance with an LBI).
Contractor employees assigned to a Level 2C position shall undergo a Limited Background Investigation (LBI).

[ ] Level 1C: Non Sensitive (Requires Suitability Determination with an NACI).
Contractor employees assigned to a Level 1C position are subject to a National Agency Check and Inquiry Investigation (NACI).

Contractor employees who have met investigative requirements within the past five years may only require an updated or upgraded investigation.

(b) **Information Technology (IT) System Security Program**

The offeror's proposal must:

(1) Include a detailed outline (commensurate with the size and complexity of the requirements of the SOW) of its present and proposed IT systems security program;

(2) Demonstrate that it complies with the AISSP security requirements, the Computer Security Act of 1987; Office of Management and Budget (OMB) Circular A-130, Appendix III, "Security of Federal Automated Information Systems;" and the DHHS AISSP Handbook.

At a minimum, the offeror's proposed information technology systems security program must address the minimum requirements identified in the DHHS AISSP Handbook, Exhibit III-A, Matrix of Minimum Security Safeguards that correspond with the Overall Security Level identified in the specific RFP.

(3) Include an acknowledgment of its understanding of the security requirements.

(4) Provide similar information for any proposed subcontractor developing or accessing an AIS.

(c) **Required Training for IT Systems Security**

DHHS policy requires that contractors receive security training commensurate with their responsibilities for performing work under the terms and conditions of their contractual agreements.

The successful offeror will be responsible for assuring that each contractor employee has completed the following NIH Computer Security Awareness Training course prior to performing any contract work: http://irtsectraining.nih.gov/. The contractor will be required to maintain a listing of all individuals who have completed this training and submit this listing to the Government.

Additional security training requirements commensurate with the position may be required as defined in OMB Circular A-130 or NIST Special Publication 800-16, "Information Technology Security Training Requirements." These documents provide information about IT security training that may be useful to potential offerors.

If the following is applicable, the specific RFP shall so state.

(d) **Prospective Offeror Non-Disclosure Agreement**

The Government has determined that prospective offerors will require access to sensitive information described below* in order to prepare an offer.

Any individual having access to this information must possess a valid and current suitability determination at the following level:*

[ ] Level 6C: Sensitive - High Risk
[ ] Level 5C: Sensitive - Moderate Risk

The specific RFP will provide a description of the sensitive information and will indicate the appropriate Position Sensitivity designation.

To be considered for access to this sensitive information, a prospective offeror must:

(1) Submit a written request to the Contracting Officer identified in the solicitation;
(2) Complete and submit the "Prospective Offeror Non-Disclosure Agreement" provided as an attachment in Section J of this solicitation; and
(3) Receive written approval from the Contracting Officer.

Prospective offerors are required to process their requests for access, receive Government approval, and then access the sensitive information within the period of time provided in the solicitation for the preparation of offers.

Nothing in this provision shall be construed, in any manner, by a prospective offeror as an extension to the stated date, time, and location in the solicitation for the submission of offers.

(e) **References**

The following documents are electronically accessible:

(1) OMB Circular A-130, Appendix III: http://csrc.ncsl.nist.gov/secplcy/a130app3.txt
(2) DHHS AISSP Handbook: http://irm.cit.nih.gov/policy/aissp.html
(3) DHHS Personnel Security/Suitability Handbook: http://www.hhs.gov/ohr/manual/pssh.pdf
(4) NIH Applications/Systems Security Template:
http://irm.cit.nih.gov/security/secplantemp.html
(5) NIST Special Publication 800-16, "Information Technology Security Training Requirements:"
http://csrc.nist.gov/publications/nistpubs/800-16/800-16.pdf
(6) NIH CIT-Policies, Guidelines and Regulations:
Table 1 - Categories of Safeguarded Agency Information:
http://irm.cit.nih.gov/security/table1.htm
Table 2 - Security Level Designations for Agency Information:
http://irm.cit.nih.gov/security/table2.htm
Table 3 - Positions Sensitivity Designations for Individuals Accessing Agency Information: http://irm.cit.nih.gov/security/table3.htm

IV. Business Proposal Instructions

Item 57:	*This item is applicable to all RFPs.* **BUSINESS PROPOSAL INSTRUCTIONS** (1) **Basic Cost/Price Information** The business proposal must contain sufficient information to allow the Government to perform a basic analysis of the proposed cost or price of the work. This information shall include the amounts of the basic elements of the proposed cost or price. These elements will include, as applicable, direct labor, fringe benefits, travel, materials, subcontracts, purchased parts, shipping, indirect costs and rate, fee, and profit.
Item 58:	*If this item is applicable, SECTION L.IV. of the specific RFP shall so state.* (2) **Proposal Cover Sheet** The following information shall be provided on the first page of your pricing proposal: 1. Solicitation, contract, and/or modification number; 2. Name and address of Offeror; 3. Name and telephone number of point of contact; 4. Name, address, and telephone number of Contract Administration Office, (if available); 5. Name, address, and telephone number of Audit Office (if available); 6. Proposed cost and/or price; profit or fee (as applicable); and total; 7. The following statement: By submitting this proposal, the offeror, if selected for discussions, grants the contracting officer or an authorized representative the right to examine, at any time before award, any of those books, records, documents, or other records directly pertinent to the information requested or submitted. 8. Date of submission; and 9. Name, title and signature of authorized representative. This cover sheet information is for use by offerors to submit information to the Government when cost or pricing data are not required but information to help establish price reasonableness or cost realism is necessary. Such information is not considered cost or pricing data, and shall not be certified in accordance with FAR 15.406-2.
Item 59:	*If this item is applicable, SECTION L.IV. of the specific RFP shall so state.* (3) **Information Other than Cost or Pricing Data** a) The information submitted shall consist of data to permit the Contracting Officer and authorized representatives to determine price reasonableness or cost realism, e.g., information to support an analysis of material costs (when sufficient information on labor and overhead rates is already available), or information on prices and quantities at which the offeror has previously sold the same or similar items. Any information submitted must support the price proposed. Include sufficient detail or cross references to clearly establish the relationship of the information provided to the price proposed. Support any information provided by explanations or supporting rational as needed to permit the Contracting Officer and authorized representative to evaluate the documentation. [Unless otherwise stated in this solicitation, the information may be submitted in the offeror's own format.]

Item 60:	*If this item is applicable, SECTION L.IV. of the specific RFP shall so state.*

b) The information submitted shall be at the level of detail described below.

1. **Direct Labor**

   Provide a time-phased (e.g., monthly, quarterly, etc.) breakdown of labor hours, rates, and cost by appropriate category. Key personnel will be separately estimated as above and identified. Give the basis for the estimates in each case.

2. **Materials**

   Provide a consolidated price summary of individual material quantities included in the various tasks, orders, or contract line items being proposed and the basis for pricing (vendor quotes, invoice prices, etc.).

3. **Subcontracted Items**

   Include parts, components, assemblies, and services that are to be produced or performed by others in accordance with offeror's design, specifications, or direction and that are applicable only to the prime contract. For each subcontract over $550,000, the support should provide a listing by source, item, quantity, price, type of subcontract, degree of competition, and basis for establishing source and reasonableness of price, as well as the results of review and evaluation of subcontract proposals when required by FAR 15.404-3.

4. **Raw Materials**

   Consists of material in a form or state that requires further processing. Provide priced quantities of items required for the proposal.

5. **Purchased Parts**

   Includes material items not covered above. Provide priced quantities of items required for the proposal.

6. **Fringe Benefits**

   Show fringe benefits as a separate line item. Include the rate(s) and/or method of calculating fringe benefits. Provide a copy of your fringe benefit rate or institutional guidelines.

7. **Indirect Costs**

   Indicate how offeror has computed and applied offeror's indirect costs, including cost breakdowns, and provide a basis for evaluating the reasonableness of proposed rates. Indicate the rates used and provide an appropriate explanation. Where a rate agreement exists, provide a copy.

8. **Special Equipment**

   If direct charge, list any equipment proposed including description, price, quantity, total price, purchase or lease, and the basis for pricing.

9. **Travel**

   Provide the cost of travel including destination, duration, purpose, per diem, transportation, and the basis for pricing.

10. **Other Costs**

    List all other costs not otherwise included in the categories described above (e.g., computer services, consultant services) and provide basis for pricing.

Item 61:	*If this item is applicable, SECTION L.IV. of the specific RFP shall so state. (Note to Offerors: If SECTION L.I. of the specific RFP has indicated that "Just in Time" procedures apply, the following data will be submitted as outlined therein.)* (4) **Cost and Pricing Data** 1. **General Instructions** A. You must provide the following information on the first page of your pricing proposal: (1) Solicitation, contract, and/or modification number; (2) Name and address of offeror; (3) Name and telephone number of point of contact; (4) Name of contract administration office (if available); (5) Type of contract action (that is, new contract, change order, price revision/redetermination, letter contract, unpriced order, or other); (6) Proposed cost; profit or fee; and total; (7) Whether you will require the use of Government property in the performance of the contract, and, if so, what property; (8) Whether your organization is subject to cost accounting standards; whether your organization has submitted a CASB Disclosure Statement, and if it has been determined adequate; whether you have been notified that you are or may be in noncompliance with your Disclosure Statement or CAS, and, if yes, an explanation; whether any aspect of this proposal is inconsistent with your disclosed practices or applicable CAS, and, if so, an explanation; and whether the proposal is consistent with your established estimating and accounting principles and procedures and FAR Part 31, Cost Principles, and, if not, an explanation; (9) The following statement: This proposal reflects our estimates and/or actual costs as of this date and conforms with the instructions in FAR 15.403-5(b)(1) and Table 15-2. By submitting this proposal, we grant the Contracting Officer and authorized representative(s) the right to examine, at any time before award, those records, which include books, documents, accounting procedures and practices, and other data, regardless of type and form or whether such supporting information is specifically referenced or included in the proposal as the basis for pricing, that will permit an adequate evaluation of the proposed price; (10) Date of submission; and (11) Name, title and signature of authorized representative. B. In submitting your proposal, you must include an index, appropriately referenced, of all the cost or pricing data and information accompanying or identified in the proposal. In addition, you must annotate any future additions and/or revisions, up to the date of agreement on price, or an earlier date agreed upon by the parties, on a supplemental index. C. As part of the specific information required, you must submit, with your proposal, cost or pricing data (that is, data that are verifiable and factual and otherwise as defined at FAR 15.401). You must clearly identify on your cover sheet that cost or pricing data are included as part of the proposal. In addition, you must submit with your proposal any information reasonably required to explain your estimating process, including-- (1) The judgmental factors applied and the mathematical or other methods used in the estimate, including those used in projecting from known data; and (2) The nature and amount of any contingencies included in the proposed price. D. You must show the relationship between contract line item prices and the total contract price. You must attach cost-element breakdowns for each proposed line item, using the appropriate format prescribed in the "Formats for Submission of Line Item Summaries'' section of this table. You must furnish supporting breakdowns for each cost element, consistent with your cost accounting system. E. When more than one contract line item is proposed, you must also provide summary total amounts covering all line items for each element of cost. F. Whenever you have incurred costs for work performed before submission of a proposal, you must identify those costs in your cost/price proposal.

G. If you have reached an agreement with Government representatives on use of forward pricing rates/factors, identify the agreement, include a copy, and describe its nature.

H. As soon as practicable after final agreement on price or an earlier date agreed to by the parties, but before the award resulting from the proposal, you must, under the conditions stated in FAR 15.406-2, submit a Certificate of Current Cost or Pricing Data.

2. **Cost Elements**

Depending on your system, you must provide breakdowns for the following basic cost elements, as applicable:

A. **Materials and services**. Provide a consolidated priced summary of individual material quantities included in the various tasks, orders, or contract line items being proposed and the basis for pricing (vendor quotes, invoice prices, etc.). Include raw materials, parts, components, assemblies, and services to be produced or performed by others. For all items proposed, identify the item and show the source, quantity, and price. Conduct price analyses of all subcontractor proposals. Conduct cost analyses for all subcontracts when cost or pricing data are submitted by the subcontractor. Include these analyses as part of your own cost or pricing data submissions for subcontracts expected to exceed the appropriate threshold in FAR 15.403-4. Submit the subcontractor cost or pricing data as part of your own cost or pricing data as required in paragraph 2.A(2) of this table. These requirements also apply to all subcontractors if required to submit cost or pricing data.

(1) *Adequate Price Competition*. Provide data showing the degree of competition and the basis for establishing the source and reasonableness of price for those acquisitions (such as subcontracts, purchase orders, material order, etc.) exceeding, or expected to exceed, the appropriate threshold set forth at FAR 15.403-4 priced on the basis of adequate price competition. For interorganizational transfers priced at other than the cost of comparable competitive commercial work of the division, subsidiary, or affiliate of the contractor, explain the pricing method (see FAR 31.205-26(e)).

(2) *All Other*. Obtain cost or pricing data from prospective sources for those acquisitions (such as subcontracts, purchase orders, material order, etc.) exceeding the threshold set forth in FAR 15.403-4 and not otherwise exempt, in accordance with FAR 15.403-1(b) (i.e., adequate price competition, commercial items, prices set by law or regulation or waiver). Also provide data showing the basis for establishing source and reasonableness of price. In addition, provide a summary of your cost analysis and a copy of cost or pricing data submitted by the prospective source in support of each subcontract, or purchase order that is the lower of either $10,000,000 or more, or both more than the pertinent cost or pricing data threshold and more than 10 percent of the prime contractor's proposed price. The Contracting Officer may require you to submit cost or pricing data in support of proposals in lower amounts. Subcontractor cost or pricing data must be accurate, complete and current as of the date of final price agreement, or an earlier date agreed upon by the parties, given on the prime contractor's Certificate of Current Cost or Pricing Data. The prime contractor is responsible for updating a prospective subcontractor's data. For standard commercial items fabricated by the offeror that are generally stocked in inventory, provide a separate cost breakdown, if priced based on cost. For interorganizational transfers priced at cost, provide a separate breakdown of cost elements. Analyze the cost or pricing data and submit the results of your analysis of the prospective source's proposal. When submission of a prospective source's cost or pricing data is required as described in this paragraph, it must be included along with your own cost or pricing data submission, as part of your own cost or pricing data. You must also submit any other cost or pricing data obtained from a subcontractor, either actually or by specific identification, along with the results of any analysis performed on that data.

B. **Direct Labor**. Provide a time-phased (e.g., monthly, quarterly, etc.) breakdown of labor hours, rates, and cost by appropriate category, and furnish bases for estimates.

C. **Indirect Costs**. Indicate how you have computed and applied your indirect costs, including cost breakdowns. Show trends and budgetary data to provide a basis for evaluating the reasonableness of proposed rates. Indicate the rates used and provide an

appropriate explanation.

D. **Other Costs**. List all other costs not otherwise included in the categories described above (e.g., special tooling, travel, computer and consultant services, preservation, packaging and packing, spoilage and rework, and Federal excise tax on finished articles) and provide bases for pricing.

E. **Royalties**. If royalties exceed $1,500, you must provide the following information on a separate page for each separate royalty or license fee:

(1) Name and address of licensor.
(2) Date of license agreement.
(3) Patent numbers.
(4) Patent application serial numbers, or other basis on which the royalty is payable.
(5) Brief description (including any part or model numbers of each contract item or component on which the royalty is payable).
(6) Percentage or dollar rate of royalty per unit.
(7) Unit price of contract item.
(8) Number of units.
(9) Total dollar amount of royalties.
(10) If specifically requested by the Contracting Officer, a copy of the current license agreement and identification of applicable claims of specific patents (see FAR 27.204 and 31.205-37).

F. **Facilities Capital Cost of Money**. When you elect to claim facilities capital cost of money as an allowable cost, you must submit Form CASB-CMF and show the calculation of the proposed amount (see FAR 31.205-10).

3. **Formats for Submission of Line Item Summaries**

**Note to Offeror: If the format set forth in the paragraph below is not applicable, SECTION L.IV of the specific RFP will specify the appropriate format.*

The detailed breakdown shall be in the format as shown on the form **Breakdown of Proposed Estimated Cost (plus fee) and Labor Hours** (Section J, List of Attachments). For each separate cost estimate, the offeror must furnish a breakdown by cost element as indicated above. In addition, summary total amounts shall be furnished. In the event the RFP cites specific line items, by number, a cost breakdown for each line item must be furnished.

4. There is a clear distinction between submitting cost or pricing data and merely making available books, records, and other documents without identification. The requirement for submission of cost or pricing data is met when all accurate cost or pricing data reasonably available to the offeror have been submitted, either actually or by specific identification, to the Contracting Officer or an authorized representative. As later information comes into your possession, it should be submitted promptly to the Contracting Officer in a manner that clearly shows how the information relates to the offeror's price proposal. The requirement for submission of cost or pricing data continues up to the time of agreement on price, or an earlier date agreed upon between the parties if applicable.

5. By submitting your proposal, you grant the Contracting Officer or an authorized representative the right to examine records that formed the basis for the pricing proposal. That examination can take place at any time before award. It may include those books, records, documents, and other types of factual information (regardless of form or whether the information is specifically referenced or included in the proposal as the basis for pricing) that will permit an adequate evaluation of the proposed price.

**Note to Offeror: The following statement is applicable IF the specific RFP includes "Just in Time" procedures.*

Data substantiating the costs or prices proposed (i.e. payroll documentation, vendor quotes, invoice price, etc.) shall not be submitted with the initial proposal. This information will be requested from the offeror during the negotiation process. The initial proposal need only indicate from what source the proposed costs and prices are substantiated.

Item 62:	*If this item is applicable, SECTION L.IV of the specific RFP shall so state.* (5) **Requirements for Cost or Pricing Data or Information Other than Cost and Pricing Data** [FAR Clause 52.215-20 (October 1997)] (a) Exceptions from cost or pricing data. (1) In lieu of submitting cost or pricing data, offerors may submit a written request for exception by submitting the information described in the following subparagraphs. The Contracting Officer may require additional supporting information, but only to the extent necessary to determine whether an exception should be granted, and whether the price is fair and reasonable. (i) Identification of the law or regulation establishing the price offered. If the price is controlled under law by periodic rulings, reviews, or similar actions of a governmental body, attach a copy of the controlling document, unless it was previously submitted to the contracting office. (ii) Commercial item exception. For a commercial item exception, the offeror shall submit, at a minimum, information on prices at which the same item or similar items have previously been sold in the commercial market that is adequate for evaluating the reasonableness of the price for this acquisition. Such information may include– (A) For catalog items, a copy of or identification of the catalog and its date, or the appropriate pages for the offered items, or a statement that the catalog is on file in the buying office to which the proposal is being submitted. Provide a copy or describe current discount policies and price lists (published or unpublished), e.g., wholesale, original equipment manufacturer, or reseller. Also explain the basis of each offered price and its relationship to the established catalog price, including how the proposed price relates to the price of recent sales in quantities similar to the proposed quantities; (B) For market-priced items, the source and date or period of the market quotation or other basis for market price, the base amount, and applicable discounts. In addition, describe the nature of the market; (C) For items included on an active Federal Supply Service Multiple Award Schedule contract, proof that an exception has been granted for the schedule item. (2) The offeror grants the Contracting Officer or an authorized representative the right to examine, at any time before award, books, records, documents, or other directly pertinent records to verify any request for an exception under this provision, and the reasonableness of price. For items priced using catalog or market prices, or law or regulation, access does not extend to cost or profit information or other data relevant solely to the offeror's determination of the prices to be offered in the catalog or marketplace. (b) Requirements for cost or pricing data. If the offeror is not granted an exception from the requirement to submit cost or pricing data, the following applies: (1) The offeror shall prepare and submit cost or pricing data and supporting attachments in accordance with Table 15-2 of FAR 15.408.* (2) As soon as practicable after agreement on price, but before contract award (except for unpriced actions such as letter contracts), the offeror shall submit a Certificate of Current Cost or Pricing Data, as prescribed by FAR 15.406-2. **Note to Offeror: If paragraph "(4) Cost and Pricing Data", subparagraph "3. Formats for Submission of Line Item Summaries" (set forth in Item 53, above) requires submission of cost information in a format other than that defined in Table 15-2 of FAR 15.408, Alternate I, below is applicable to the solicitation.* **Alternate I** (October 1997). As prescribed in 15.408(l), substitute the following paragraph (b)(1) for paragraph (b)(1) of the basic provision:

	(b)(1) The offeror shall submit cost or pricing data and supporting attachments in the following format: The format specified in paragraph L.IV.(4) Cost and Pricing Data, subparagraph 3. Formats for Submission of Line Item Summaries shall be used for the submission cost information. Submission of all other cost or pricing data shall be in accordance with Table 15-2 in FAR 15.408.
Item 63:	*If this item is applicable, SECTION L.IV. of the specific RFP shall so state. (Note to Offerors: If SECTION L.I. of the specific solicitation has indicated that "Just in Time" procedures apply, the following data will be submitted as outlined therein.)* (6) **Total Compensation Plan - Instructions** a) Total compensation (salary and fringe benefits) of professional employees under service contracts may, in some cases, be lowered by recompetition of these contracts. Lowering of compensation can be detrimental in obtaining the necessary quality of professional services needed for adequate performance of service contracts. It is, therefore, in the best interest of the Government that professional employees, as defined in 29 CFR Part 541, be properly compensated in these contracts. All offerors [included in the competitive range will be required to/as a part of their business proposal] will submit a "Total Compensation Plan" (salaries and fringe benefits) for these professional employees for evaluation purposes. b) The Government will evaluate the Total Compensation Plan to ensure that this compensation reflects a sound management approach and an understanding of the requirements to be performed. It will include an assessment of the offeror's ability to provide uninterrupted work of high quality. The total compensation proposed will be evaluated in terms of enhancing recruitment and retention of personnel and its realism and consistency with a total plan for compensation (both salaries and fringe benefits). c) Evaluation for award, therefore, will include an assessment of the Total Compensation Plan submitted by each offeror. (7) **Total Compensation Plan - Evaluation** a) **Total Compensation Plan (Professional Employees)** In establishing compensation levels for professional employees, the total compensation (both salaries and fringe benefits) proposed shall reflect a clear understanding of the requirements of the work to be accomplished and the suitability of the proposed compensation structure to obtain and retain qualified personnel to meet mission objectives. The salary rates or ranges must recognize the distinct differences in professional skills and the complexity of varied disciplines as well as job difficulty. Proposals offering total compensation levels less than currently being paid by the predecessor Contractor for the same work will be evaluated, in addition to the above, on the basis of maintaining program continuity, uninterrupted work of high quality, and availability of required competent professional employees. Offerors are cautioned that instances of lowered compensation for essentially the same professional work may be considered a lack of sound management judgment in addition to indicating a lack of understanding of the requirement. b) **Cost (Professional Compensation)** Proposals which are unrealistically low or do not reflect a reasonable relationship of compensation to the professional job categories so as to impair the Contractor's ability to recruit and retain competent professional employees, may be viewed as reflecting a failure to comprehend the complexity of the contract requirements. The Government is concerned with the quality and stability of the work force to be employed on this contract. The compensation data required will be used in evaluation of the offeror's understanding of the contract requirements. c) **Other (Labor Relations)** An assessment of the potential for adverse effect upon performance and maintenance of the required number of professional employees with requisite skills resulting from an unrealistically

	low compensation structure will also be made. d) **Federal Acquisition Regulation Clauses incorporated by Reference** FAR Clause 52.222-46, Evaluation of Compensation for Professional Employees (FEBRUARY 1993).
Item 64:	*The following item is applicable to all RFPs.* (8) **Qualifications of the Offeror** You are requested to submit a summary of your "General Experience, Organizational Experience Related to this RFP, Performance History and Pertinent Contracts." a) **General Experience** **General experience** is defined as general background, experience and qualifications of the offeror. A discussion of proposed facilities which can be devoted to the project may be appropriate. b) **Organizational Experience Related to the RFP** **Organizational experience** is defined as the accomplishment of work, either past or on-going, which is comparable or related to the effort required by this RFP. This includes overall offeror or corporate experience, **but not** the experience and/or past performance of individuals who are proposed as personnel involved with the Statement of Work in this RFP. c) **Performance History** **Performance history** is defined as meeting contract objectives within delivery and cost schedules on efforts, either past or on-going, which is comparable or related to the effort required by this RFP. d) **Pertinent Contracts** **Pertinent contracts** is defined as a listing of each related contract completed within the last three years or currently in process. The listing should include: 1) the contract number; 2) contracting agency; 3) contract dollar value; 4) dates contract began and ended (or ends); 5) description of contract work; 6) explanation of relevance of work to this RFP; 7) actual delivery and cost performance versus delivery and cost agreed to in the contract(s). For award fee contracts, separately state in dollars the base fee and award fee available and the award fee actually received. The same type of organizational experience and past performance data should be submitted. e) **Pertinent Grants** List grants supported by the Government that involved similar or related work to that called for in this RFP. Include the grant number, involved agency, names of the grant specialist and the Science Administrator, identification of the work, and when performed. You are cautioned that omission or an inadequate or inaccurate response to this very important RFP requirement could have a negative effect on the overall selection process. Experience and past performance are factors which are relevant to the ability of the offerors to perform and are considered in the source selection process. (9) **Other Administrative Data** a) **Property** (1) It is DHHS policy that Contractors will provide all equipment and facilities necessary for performance of contracts. Exception may be granted to furnish Government-owned property, or to authorize purchase with contract funds, only when approved by the Contracting Officer. If the offeror is proposing that the Government provide any equipment, other than that specified under Government Furnished Property in the RFP,

	the proposal must include comprehensive justification which includes: (a) An explanation that the item is for a special use essential to the direct performance of the contract and the item will be used exclusively for the purpose. Office equipment such as desks, office machines, etc., will not be provided under a contract except under very exceptional circumstances. (b) No practical or economical alternative exists (e.g., rental, capital investment) that can be used to perform the work. (2) The offeror shall identify Government-owned property in its possession and/or Contractor titled property acquired from Federal funds, which it proposes to use in the performance of the prospective contract. (3) The management and control of any Government property shall be in accordance with DHHS Publication (OS) 686 entitled, "Contractor's Guide for Control of Government Property (1990)," a copy of which will be provided upon request. b) **Submission of Electronic Funds Transfer Information with Offer, FAR Clause 52.232-38**, (May 1999) The offeror shall provide, with its offer, the following information that is required to make payment by electronic funds transfer (EFT) under any contract that results from this solicitation. This submission satisfies the requirement to provide EFT information under paragraphs (b)(1) and (j) of the clause at 52.232-34, Payment by Electronic Funds Transfer--Other than Central Contractor Registration. (1) The solicitation number (or other procurement identification number). (2) The offeror's name and remittance address, as stated in the offer. (3) The signature (manual or electronic, as appropriate), title, and telephone number of the offeror's official authorized to provide this information. (4) The name, address, and 9-digit Routing Transit Number of the offeror's financial agent. (5) The offeror's account number and the type of account (checking, savings, or lockbox). (6) If applicable, the Fedwire Transfer System telegraphic abbreviation of the offeror's financial agent. (7) If applicable, the offeror shall also provide the name, address, telegraphic abbreviation, and 9-digit Routing Transit Number of the correspondent financial institution receiving the wire transfer payment if the offeror's financial agent is not directly on-line to the Fedwire and, therefore, not the receiver of the wire transfer payment. c) **Financial Capacity** The offeror shall indicate if it has the necessary financial capacity, working capital, and other resources to perform the contract without assistance from any outside source. If not, indicate the amount required and the anticipated source.
Item 65:	*The following item is applicable to commercial organizations.* d) **Facilities Capital Cost of Money**, FAR 52.215-16, (June 2003) (a) Facilities capital cost of money will be an allowable cost under the contemplated contract, if the criteria for allowability in FAR 31.205-10(b) are met. One of the allowability criteria requires the prospective Contractor to propose facilities capital cost of money in its offer. (b) If the prospective Contractor does not propose this cost, the resulting contract will include the clause Waiver of Facilities Capital Cost of Money. (End of Provision) If the offeror elects to claim this cost, the offeror shall specifically identify or propose it in the cost proposal for the contract by checking the appropriate box below. **[ ]** The prospective Contractor has specifically identified or proposed facilities capital cost of money in its cost proposal and elects to claim this cost as an allowable cost under the contract. Submit Form CASB-CMF (see FAR 31.205-10). **[ ]** The prospective Contractor has not specifically identified or proposed facilities capital cost of money in its proposal and elects not to claim it as an allowable cost under the contract.

Item 66:	*If this item is applicable, SECTION L.V. of the specific RFP shall so state.* e) **Royalties** The offeror shall furnish information concerning royalties which are anticipated to be paid in connection with performance of work under the proposed contract.
Item 67:	*If this item is applicable, SECTION L.V. of the specific RFP shall so state.* e) **Incremental Funding** An incrementally funded cost-reimbursement contract is a contract in which the total work effort is to be performed over a multiple year period and funds are allotted, as they become available, to cover discernible phases or increments of performance. The incremental funding technique allows for contracts to be awarded for periods in excess of one year even though the total estimated amount of funds expected to be obligated for the contract are not available at the time of the contract award. If this requirement is specified elsewhere in this RFP, the offeror shall submit a cost proposal for each year. In addition, the following provisions are applicable: **HHSAR 352.232-75, Incremental Funding (January 2001)** (a) It is the Government's intention to negotiate and award a contract using the incremental funding concepts described in the clause entitled Limitation of Funds. Under the clause, which will be included in the resultant contract, initial funds will be obligated under the contract to cover the first year of performance. Additional funds are intended to be allotted to the contract by contract modification, up to and including the full estimated cost of the contract, to accomplish the entire project. While it is the Government's intention to progressively fund this contract over the entire period of performance up to and including the full estimated cost, the Government will not be obligated to reimburse the Contractor for costs incurred in excess of the periodic allotments, nor will the Contractor be obligated to perform in excess of the amount allotted. (b) The Limitation of Funds clause to be included in the resultant contract shall supersede the Limitation of Cost clause found in the General Provisions. (End of provision)
Item 68:	*This item is applicable to all RFPs.* (10) **Subcontractors** If subcontractors are proposed, please include a commitment letter from the subcontractor detailing: a) Willingness to perform as a subcontractor for specific duties (list duties). b) What priority the work will be given and how it will relate to other work. c) The amount of time and facilities available to this project. d) Information on their cognizant field audit offices. e) How rights to publications and patents are to be handled. f) A complete cost proposal in the same format as the offeror's cost proposal. Note: Organizations that plan to enter into a subcontract with an educational concern under a contract awarded under this RFP should refer to the following Web Site for a listing of clauses that are required to be incorporated in Research & Development (R&D) subcontracts with educational institutions: http://ocm.od.nih.gov/contracts/rfps/FDP/FDPclausecover.htm

	(11) **Proposer's Annual Financial Report** A copy of the organization's most recent annual report must be submitted as part of the business proposal. For solicitations using "Just in Time" procedures, only those offerors included in the competitive range will be required to submit a copy of the organization's most recent annual financial report. (12) **Representations and Certifications** One copy of the Representations and Certifications attached as Section K shall be completed and be signed by an official authorized to bind your organization. Additionally, a completed copy of the Representations and Certifications shall be submitted from any proposed subcontractor. (13) **Travel Costs / Travel Policy** a) **Travel Costs - Commercial** ***Note to Offeror:** This paragraph is applicable to Commercial Organizations only.* Costs for lodging, meals, and incidental expenses incurred by Contractor personnel shall be considered to be reasonable and allowable to the extent they do not exceed on a daily basis the per diem rates set forth in the Federal Travel Regulations, General Services Administration (GSA). Therefore, if travel costs are applicable and proposed by offerors, please be advised that they shall be calculated using the per diem rate schedule as established by GSA. Reimbursement of travel costs under any contract awarded from this RFP shall be in accordance with FAR 31.205-46. b) **Travel Policy** One copy of the offeror's (and any proposed subcontractor's) written travel policy shall be included in the business proposal (original only). If an offeror (or any proposed subcontractor) does not have a written travel policy, the offeror shall so state. *Note to Offerors: For RFPs using "Just in Time" procedures, substitute the following paragraph.* Only those offerors included in the competitive range will be required to submit one copy of their written travel policy. A written travel policy for any proposed subcontractors shall also be submitted at that time. If an offeror (or any proposed subcontractor) does not have a written travel policy, the offeror shall so state.
Item 69:	*If this item is applicable, Section L.IV. of the specific RFP shall so state.* (14) **Certification of Visas for Non-U.S. Citizens** Proposed personnel under research projects are not required to be citizens of the United States. However, if non-U.S. citizens are proposed under a contract to be performend in the United States and its outlying areas, then the offeror must indicate in the proposal that these individuals have the required visas.